

**IMPLEMENTATION OF THE TOXIC SUBSTANCES
CONTROL ACT**

**HEARING
BEFORE THE
SUBCOMMITTEE ON
TOXIC SUBSTANCES AND ENVIRONMENTAL
OVERSIGHT
OF THE
COMMITTEE ON
ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE
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(II)

CONTENTS

Gorton, Hon. Slade, U.S. Senator from the State of Washington, opening statement of	Page 1
---	-----------

WITNESSES

Davies, Dr. J. Clarence, executive vice president, Conservation Foundation.....	17
Prepared statement	32
Hurst, E. Hamilton, vice president, environment and health, Nalco Chemical Co., representing Chemical Manufacturers Association	23
Prepared statement	61
Scott, Michael J., general counsel, Mooney Chemicals, Inc.....	27
Prepared statement	83
Todhunter, Dr. John A., Assistant Administrator for Pesticides and Toxic Substances, Environmental Protection Agency	2
Warren, Jacqueline M., natural resources defense council	19
Prepared statement	42

ADDITIONAL MATERIAL

Environmental Protection Agency, Office of Toxic Substances, "New Chemicals Program," an excerpt from the report entitled, "Priorities For OTS Operation"	103
---	-----

IMPLEMENTATION OF THE TOXIC SUBSTANCES CONTROL ACT

WEDNESDAY, AUGUST 4, 1982

U.S. SENATE, COMMITTEE ON ENVIRONMENT AND PUBLIC
WORKS, SUBCOMMITTEE ON TOXIC SUBSTANCES AND EN-
VIRONMENTAL OVERSIGHT,

Washington, D.C.

The subcommittee met at 2:05 p.m., in room 4200, Dirksen
Senate Office Building, Hon. Slade Gorton (chairman) presiding.

Present: Senators Gorton and Baucus.

OPENING STATEMENT OF HON. SLADE GORTON, U.S. SENATOR FROM THE STATE OF WASHINGTON

Senator GORTON. Good afternoon. This is a hearing of the Subcommittee on Toxic Substances and Environmental Oversight. The purpose of today's hearing is to receive testimony on the Environmental Protection Agency's implementation of the Toxic Substances Control Act.

There is general consensus that the EPA, under the previous administration, was slow in implementing TSCA. There are, however, indications that EPA, under the current administration, has begun to increase its pace and I hope that that will continue. I am aware that this administration's approach to implementing this complex and important law differs significantly from that of the preceding administration. The subcommittee is, of course, interested in hearing the witnesses' views on the implementation of TSCA generally, but we are especially interested in learning the nature of, and bases for, the very fundamental changes EPA is making in its approach to the management of toxic substances.

One of the most visible and far reaching of these changes is EPA's demonstrated intent to minimize rulemaking and to rely instead on voluntary compliance. For example, EPA has begun negotiating voluntary testing agreements in lieu of developing rules under section 4 of TSCA. I hope that Dr. Todhunter will describe this procedure to us today and will explain the way other TSCA requirements, which are keyed to section 4 rulemaking, will be implemented where a voluntary testing agreement is substituted for a section 4 rule.

Similarly, section 6 of TSCA requires EPA to control unreasonable risks exposure to existing chemicals. EPA, under both the previous and current administrations, has left virtually unused the considerable discretionary powers of section 6. I understand that the Agency may now be planning to extend the concept of negotiat-

ed or voluntary controls to risk analyses under section 6. Hopefully, we will hear today whether and how EPA expects to use nonregulatory alternatives to control risks from existing chemicals. As with section 4, I am interested to learn how other provisions of TSCA, which come into play when a rule is promulgated under section 6, will be satisfied if a negotiated or voluntary response by industry is substituted for section 6 rulemaking.

I hope that the witnesses before the subcommittee today will discuss premanufacture notification process. EPA should be able to make a meaningful review of each new chemical before it is manufactured in order to predict and prevent unreasonable risks of injury to health or the environment. There have been reports that EPA has been basing its review of premanufacture notifications on incomplete data. Hopefully, Dr. Todhunter will inform us about the completeness and adequacy of manufacturer information submitted at the time of premanufacture notification.

These several issues are, of course, only some of those which are raised by implementation of the Toxic Substances Control Act. We look forward to testimony from Dr. Todhunter, and from several other witnesses today. We will begin with our first witness, Dr. Todhunter, at this time.

You may proceed.

STATEMENT OF DR. JOHN A. TODHUNTER, ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY

Dr. TODHUNTER. Thank you very much, Mr. Chairman.

Mr. Chairman, I am glad to have the opportunity this afternoon to discuss with you the status of the Toxic Substances Control Act and our efforts within this program area. As you know, this act was enacted in 1976. However, when I came to EPA, I found that not much progress had been made in its implementation.

This administration is interested in environmental results—not indecision. We therefore set about to create strategies, set policy, and publish rules to insure that the Toxic Substances Control Act produces those results in a cost-effective manner. While I won't take time this afternoon to list all we have accomplished over the last year, I would like to highlight a few actions:

During fiscal year 1982, this administration has—among other things:

Issued final rules and proposed Agency policy on the information gathering provisions of TSCA which the previous administration was unable to move. We have:

Issued a final rule requiring manufacturers of some 250 chemicals to submit production, use, and exposure data to the Agency; and

Proposed generic definitions of small businesses to exempt those small organizations for which reporting would be an undue burden without sacrificing the Agency's need for an access to all pertinent data.

We have met court-ordered schedules and legislative deadlines.

In this regard we have met all court-ordered schedules for the previous administration's backlog of responses to the Interagency Testing Committee, or ITC;

We have met every legislative deadline for responses to current ITC designated candidates for chemical testing; and

We are currently meeting court-ordered schedules for reproposal of portions of the PCB regulations which were successfully challenged in court under previous administration.

We have moved the languishing asbestos activities to the forefront of program priorities. We have issued final asbestos-in-schools rule; we have issued a final rule requiring industry reporting on asbestos production, exposure, and use, and we have established an Interagency Federal Asbestos Task Force.

We have also revamped our new chemicals program to increase harmonization with the European Economic Community's approach to new chemicals and to give priority to new chemicals which may be harmful to health or the environment either now or in the future.

We have established policy for followup of new chemicals of concern, and we have recently proposed reduced governmental review of low-risk new chemicals.

Mr. Chairman, in your letter inviting me to appear today, you asked me to elaborate on five aspects of the toxic substances control program, and I am prepared to do that now. These areas are: negotiated testing agreements for existing chemicals, possible options we may be considering for control of existing chemicals, criteria used to select the 250 chemicals about which manufacturers will have to submit production, use, and exposure data, and the status of the new chemicals program and our efforts to harmonize our approach with the European Community.

If I can turn first to the negotiated testing agreements.

Beginning with negotiated testing agreements, section 4 of TSCA requires EPA to respond within 1 year to recommendations by the interagency testing committee that certain chemicals be considered as candidates for testing for specific health and environmental effects.

Negotiated testing agreements are an alternative tool to rule-making for generating data on commercial chemicals. Parties interested in a negotiated testing approach must either sit down with EPA and work out negotiated agreements which are properly responsive to the ITC, or voluntarily incorporate ITC testing recommendations into their existing testing plans. These agreements must be in a form to propose in the Federal Register within the 1-year statutory deadline. The negotiated agreement will include a description, preferred test protocols and a schedule for completion.

Opportunities for public involvement are provided in exactly the same way whether the Agency is pursuing a negotiated agreement or conducting rulemaking. The public is encouraged to comment on publication of the ITC recommendations, to participate in a public meeting to discuss chemical-specific testing options, and to participate in a public course-setting meeting resulting in a basic decision to test or not to test. The final opportunity for public participation—whether the Agency pursues rulemaking or negotiated agreements comes with formal public comment on the proposed testing

program. Now, I have actively sought public participation in the negotiated agreement process. In fact, in one case, the comment period on a proposed negotiated agreement was extended at the request of the public interest community.

I think the greatest merit to the negotiated agreement approach is the potential for getting testing underway far more quickly than a rulemaking process which involves proposal, public comment, possible reproposal, and final rule. The speeding up of testing and the lowered adversarial atmosphere are important public benefits. The Agency still does retain its rulemaking prerogatives should they be needed for any reason.

Now, very specifically, the negotiated testing approach can lead to testing initiated within 1.5 years after ITC designation, whereas, formal rulemaking will average from 2.5 to 3 years after ITC designation. All of the test data which we expect to receive in fiscal year 1984 will come from recent negotiated agreements. Some 200 studies will be carried out by industry and data generated from these studies will be first ever received under section 4 of TSCA.

Finally, with respect to negotiated agreements, enforceability of a nonrule required test should be discussed. As a scientist, I would tell you that there is no way to enforce test results. You cannot enforce against someone whose laboratory rats die of a virus. What is enforceable, and what we intend to enforce, is adherence to good laboratory practices. On this point we are very firm. Our Office of Enforcement has devised language for those agreements which will allow governmental inspections of test facilities.

Let me turn for a moment now to the area of nonregulatory controls of existing chemicals. I would like to state at the outset that I fully intend to use section 6 authorities whenever the situation warrants. There is no plan to replace general regulatory approaches with nonregulatory approaches to chemical control.

My office is, however, always looking for effective and expeditious ways to reduce exposures to chemicals of concern and encouraging manufacturers to implement their own controls well prior to the point when exposures or toxicity might trigger a full section 6 action. Public health or environmental benefits are just as real when they result from preventive rather than regulatory cleanup action. As an illustration of my point, an interesting trend has emerged with respect to substantial risk notices submitted by manufacturers under section 8(e) notices. Partly as a result of Agency encouragement, more and more manufacturers are voluntarily controlling uses and limiting exposures to these chemicals in a variety of ways. These actions range from process handling changes to worker notification to discontinuing production. None of these actions are required by law but all are reducing exposures in a meaningful way. I have asked my staff to study other areas where such immediate environmental and health protection might be possible. And, I have also asked the staff to evaluate information-sharing methods, so that the data or experience of one manufacturer might be shared with other manufacturers and the public. I will be glad to discuss the results of these studies with the committee when they are completed.

Mr. Chairman, you have indicated interest in knowing more about the criteria used to select the chemicals covered by EPA's

recent information gathering rule. As you know, last month, EPA announced final requirements for manufacturers to supply the Agency with production, use and exposure information on 250 industrial chemicals. Now, the previous administration's original proposal was to cover some 2,226 chemicals. We felt that number was both unrealistic and unmanageable and they must have also since they quickly repropose the rule reducing the number of chemicals covered to 1,300. Even this new number did not seem to be based on rational or scientifically sound criteria.

In the interest of obtaining data primarily where there is the potential for using that data to obtain environmental results, the Agency is now requiring information on selected chemicals which have been previously reported as possibly posing substantial risks to health or the environment and on chemicals which have already been designated by the ITC.

This administration believes that Congress correctly gave the ITC primary responsibility for identifying existing chemicals of priority concern for EPA's attention. Production, use, and exposure data are crucially important to the Agency's activity concerning the ITC chemicals. This data will aid the Agency in deciding whether testing is necessary. Additionally, this data, when combined with the results of testing, will allow the Agency to link chemical-specific hazard and exposure information in making any future control decisions.

In addition to these ITC chemicals, the list of 250 chemicals subject to the information gathering rule contains certain chemicals brought to our attention under section 8(e) of TSCA. This section requires industry to notify the Agency when information is received that the chemical may present significant risks to health or the environment. Production, use, and exposure data are relevant here too so that appropriate action can be taken if warranted.

Now, with your permission, Mr. Chairman, I would like to combine the final two areas of inquiry—the premanufacture notification program and international harmonization as we see these linked hand in hand.

You asked about the quality and quantity of test data submitted with PMN's and our ability to review new chemical substances based on that data. Our experience with the PMN program indicates that while much physical-chemical data is received, relatively limited health and environmental-effects testing is performed on new chemicals prior to PMN submission. There are several reasons for the sparsity of test data in PMN's. First, many new chemicals do not warrant testing: many belong to chemical classes the biological activity of which is already well characterized; and others are produced in low volume or used in ways that lead to limited exposure, for instance, site-limited intermediates or some specialty chemicals. Second, because new chemicals are generally early in commercialization and often are not entered into commerce, they often cannot support the costs of extensive testing program.

The amount of test data submitted with PMN is not the crucial issue in our review of new chemicals. Congress in formulating section 5 of TSCA did not require that any test data be submitted with a PMN notice. As I pointed out, most new chemicals are structurally similar to an existing chemical or class of chemicals. I

am very proud of our sophisticated computer technology which, when combined with the professional judgment of the experts on my staff, can be used to evaluate structure activity relationships and to predict new chemical behavior with great accuracy.

I want to point out that Congress also gave the Agency a formal tool to obtain additional test data for new chemicals when it is needed. This is section 5(e) of TSCA and it is a tool the Agency has used in the past. More frequently, when additional data are needed, the Agency has been able to work with individual PMN submitters to obtain that data. Important uncertainties have been resolved through this kind of direct approach.

I turn now to your inquiry about the status of the Agency's response to the petition requesting exemptions from the PMN review requirements. Last week the Administrator signed two proposals which, in effect, constitutes our response. And it is at this point that I would like to bring in international harmonization. The new chemical policy which was announced last week and which incorporates the exemption proposals is designed to be consistent in goals and spirit with the European approach. This consistency is important in order to avoid unnecessary barriers to international trade and to assure that new chemicals wherever they are manufactured, are evaluated and, if necessary, controlled to provide the maximum public health and environmental protection.

Both we and our European partners realize that only by focusing resources can we be assured of identifying and taking action on those relatively few chemicals which—if they did enter the marketplace—could be harmful to health or the environment. I think all parties recognize that certain types of chemicals or chemical processes do not need extensive review. Certain compounds generally are either absorbed into living tissues or are inert or biologically inactive. Other chemicals are used in such a way that exposure is restricted. By significantly reducing governmental review of these substances, the Agency will be better able to scrutinize more closely those that remain.

Accordingly, regulations have been proposed under section 5(h)(4) that would exempt from the full 90-day PMN review certain polymers, site-limited intermediates and lowvolume chemicals which do not present unreasonable risks. Instead, we propose to substitute a 14-day Agency review. The manufacturer would also, prior to Agency review, be required to have a qualified expert assess the risks of the chemical and conclude that it would not be hazardous as used. The Agency is developing an audit program to monitor the adequacy of the qualified experts' evaluation and credentials.

Cognizant of our fundamental role to insure the public health and to protect the environment, several safeguards have been included in these proposed regulations:

First, EPA could prohibit a chemical's manufacturer if it identified a potential hazard;

Chemicals known to be or reasonably suspected of causing cancer or birth defects would be automatically ineligible for exemption;

Chemicals that might cause other adverse human or environmental effects under conditions of use would not be exempted; and

A full PMN notice and a 90-day Agency review would be required if an exempt chemical is no longer used exclusively as a site-limited intermediate or is no longer a low-volume chemical.

These safeguards and other aspects of our proposals were not part of the original petition but I believe that they are important and necessary components. If these proposals become final rules, they will assure that only clearly nonrisk chemicals are able to receive reduced review and that a high level of public health and environmental protection will be maintained more cost effectively.

I would like to emphasize that publication of the two exemption proposals was linked to announcement of EPA's new chemical followup policy. Again, this is illustrative of this administration's overall effort to focus its efforts in areas which can produce meaningful environmental results. Followup of certain new chemicals is important because while given that a chemical may pose little risk under conditions of initial manufacture, subsequent uses and exposures connected with the chemical may be of great concern.

EPA proposes to employ—whenever necessary—any one of several strong followup tools to reassess new chemicals which may cause unreasonable risks in the future. New chemicals which are covered by exemptions such as those I have just described will be reviewed by EPA once they exceed production volume or are used in ways which do not conform to the exemption conditions.

New chemicals which did not qualify for an exemption and which received full premanufacture review may be subject to one or more followup actions. EPA may at the end of the 90-day premanufacture review period require that when commercialization reaches a certain point, additional test data may be required. This would be accomplished by using TSCA section 5(e). Another followup tool is section 8(a) of TSCA. This section could be used at any time on any chemical to require all manufacturers, processors, and importers of that chemical to submit production, use, and exposure data. This information, when combined with our own projections, will allow us to decide whether additional chemical testing is necessary. A final tool could be used at the end of the 90-day premanufacture review period when the manufacturer can be required to notify EPA before any significant new uses of the chemical occur. This is allowed by section 5(a) of TSCA. As you can see, we intend to employ a variety of appropriate legislative tools when we have reason to believe that a new chemical may be of concern in the future.

With respect to your final question about coordination with the Organization of Economic Cooperation and Development Countries, the Agency has been actively involved in OECD's chemical program of harmonization since the inception of the chemicals testing program in 1977. This program was designed to promote coordinated or consistent actions among countries formulating toxic substances legislation so as to avoid the creation of nontariff trade barriers. EPA has chaired the chemicals group, the Management Committee, and two of the program's expert working groups.

In May 1980 a meeting of the chemicals group at high level was called to give guidance for future work in the program. The EPA Administrator led the U.S. delegation to this important meeting, which ultimately resulted in adoption by the OECD council of a de-

cision on mutual acceptance of data. By the terms of this decision, member States agreed that data generated in accordance with the OECD test guidelines and principles of good laboratory practice would be acceptable in member States for purposes of assessment. This was vitally important as a step to avoid the potential creation of trade barriers. In response to the decision, test standards, and guidelines published under TSCA will reference, as acceptable methods, the OECD test guidelines. Agreement also was reached in principle on the broad concept of an OECD base set of data to guide the assessment of new chemicals and negotiations continue to formulate acceptable language to put before the OECD Council.

Mr. Chairman, I would like to close by taking advantage of this opportunity to set the record straight about one aspect of our program which I feel has been misrepresented at times—and this is the area of TSCA compliance and enforcement activities. I have attached two charts to my testimony for the subcommittee's information. These charts depict actual numbers of compliance inspections and enforcement actions from October of 1978 through October of 1982.

I am very proud that both compliance inspections and enforcement actions have continued to rise under the present administration. Far from shirking our responsibilities in this area, we have maintained an aggressive posture and will do so in the future. I also would like to announce that last week we settled our first civil case under TSCA. American Cyanamid was fined \$18,750 for withholding from EPA information in its possession indicating that a specific chemical could cause significant risks therefore violating TSCA section 8(e). I hope this stands as a signal as to the seriousness of our enforcement posture when these clear violations of the law occur.

Mr. Chairman, I trust I have been able to address the subcommittee's concerns relevant to the implementation of the Toxic Substances Control Act. This concludes my prepared statement. I will be happy to answer any questions that the subcommittee may have.

[An attachment to Dr. Todhunter's statement follows:]

TOXIC SUBSTANCES CONTROL ACT - COMPLIANCE INSPECTIONS

	FY 79 ACTUAL	FY 80 ACTUAL	FY 81 ACTUAL	FY 82 PROJECTION
<u>Section 4</u> Chemical Testing Requirements			--	0
<u>Section 5</u> Premanufacture Notices			10	50
<u>Section 6</u> Chemical Control				
- PCB	677	816	1033	1715
- CFC	2	16	46	106
- Dioxin			--	94
- Asbestos			--	--
<u>Section 8</u> Information Reporting		69	5	23
<u>Sections 12 & 13</u> Export/Import		6	2	30
TOTALS	679	907	1096	2018

TOXIC SUBSTANCES CONTROL ACT - ENFORCEMENT ACTIONS

	<u>FY79</u> <u>ACTUAL</u>	<u>FY80</u> <u>ACTUAL</u>	<u>FY81</u> <u>ACTUAL</u>	<u>FY 82</u> <u>PROJECTION</u>
Number of Federal Enforcement Actions				
Civil Complainants	22	70	115	72
Criminal Prosecutions	0	2	0	0
Warning Notices	<u>45</u>	<u>102</u>	<u>112</u>	<u>247</u>
TOTALS	67	174	227	319

Senator GORTON. Thank you very much for your statement, Dr. Todhunter.

You noted in your statement some of the advantages of negotiated testing agreements over section 4 rulemaking. One of the effects of this procedure, however, could be that those sections of TSCA which would be triggered by promulgation of the section 4 rule are not triggered by voluntary testing agreements. How will these statutory requirements be satisfied where testing is done pursuant to a negotiated agreement?

Dr. TODHUNTER. I presume you are referring to the compensation sharing provision of the act?

Senator GORTON. Yes.

Dr. TODHUNTER. This is a very interesting case. As a general program, particularly for guidance, we anticipate that negotiations with several parties might not be a very fruitful sort of thing to employ. So, one of the steps that we used to evaluate whether it is worth even entering into a negotiation is the number of possible sponsors for the test.

We also do anticipate that in some cases industry itself may realize that it is to everybody's advantage to go ahead and issue a formal test rule so that we can invoke the compensation sharing provision. With a negotiated agreement, our basic assumption there would generally be a single sponsor so the compensation question will not arise or at best a limited group of sponsors that had entered into contractual obligations with each other.

Senator GORTON. The same question could apply to export notifications and disclosure of data requirement.

Dr. TODHUNTER. The export notification section had to do with control actions under sections 5, 6, or 7.

Senator GORTON. Pardon me?

Dr. TODHUNTER. The export notification action has to do with control actions under sections 5, 6, or 7.

Senator GORTON. But they are not triggered, are they?

Dr. TODHUNTER. No. A test rule would not trigger necessarily a control action until the results of the test were back and we would process the results of the test whether it were under a negotiated agreement, the same with respect to selecting a control option, as we would if it came back from a rule. The only difference would be is we would have the information far sooner.

Senator GORTON. You have also stated in your testimony that you have "no plan to replace general regulatory approaches with nonregulatory approaches to chemical control."

Dr. TODHUNTER. That is correct, I do not.

Senator GORTON. Recent trade reports have described OTS plans to develop an agreement with chemical companies to control risk by chemicals possibly using risk management advisory. Are those reports accurate?

Dr. TODHUNTER. They are not complete. The staff has been looking at the existing chemical question and one of the options that they have discussed amongst themselves is the question of voluntary compliance. I do not see how we can do it. The risk management advisory, however, is a different sort of a thing. It is not intended to replace a control action, it is rather intended to very quickly disseminate the Agency's concerns over a particular chemical hoping this will push some immediate action such that we get something going on even before necessarily we are all the way down the road to rulemaking, if rulemaking is the appropriate way to handle the problem.

Senator GORTON. Both the recent PCB rule and the proposed pre-manufacture notification exemption require that industry use qualified experts.

Dr. TODHUNTER. Yes.

Senator GORTON. To this point EPA has not disclaimed that term or given specific criteria for selecting or certifying such qualified experts. Who is going to choose them and what criteria will be used?

Dr. TODHUNTER. First of all, that is one of the issues for comment in which we are soliciting comments with the proposals we have issued.

One of the problems we looked at is the question, what if you have a very small company that cannot afford to pay some big name toxicologist to come down, look at their little resin and say, yes, that is fine? What if they have a person who has been working with that particular material or similar one for the last 10 or 15 years and he knows that product chemistry quite well, might not the person be qualified an expert on that particular substance? This is an issue for comment. We do anticipate reviewing the qualified experts' conclusions and, as I mentioned in my testimony, the enforcement program is working out details of an audit program to allow us to go back and audit in fact what these experts are doing.

Senator GORTON. How is that audit program going to work?

Dr. TODHUNTER. We do not have the details worked out. This is something that since the rules are only out in proposal now, the enforcement program has only recently begun to look at it.

Senator GORTON. How soon do you expect to set up rules and have it in place?

Dr. TODHUNTER. They are out for proposal, they went out last week. If we allow our normal comment and proposal period, it could easily be another 6 months.

Senator GORTON. On February 10 of this year you recommended to the Administrator that EPA not invoke the expedited rulemaking procedure of section 4(f) for formaldehyde. In a separate memorandum on the same day and subject you transmitted the OTS for-

maldehyde work plan and described the evaluation of hazards phase nearing completion. What is the status of your work on formaldehyde and have you reached a conclusion whether or not it is a human carcinogen?

Dr. TODHUNTER. There are two aspects. I did not recommend to the Administrator that she do one thing or another. I concurred with an existing staff recommendation on February 10. Secondly, one of our concerns is that as everyone recognizes formaldehyde certainly is carcinogen in the red but it is not a potent carcinogen. We would like to be able to expand our scope somewhat beyond the simple question of carcinogenicity. We feel by being forced to focus on that narrow channel we may miss some more important aspect of formaldehyde work. Our work plan is an interagency experience with the Center for Toxicological Research who have currently set up an information clearinghouse and have begun to pull in existing data on formaldehyde, published reports and others that address a broad issue, a broad range of health issues over and above carcinogenicity.

Senator GORTON. What kind of schedule do you anticipate for concluding that work?

Dr. TODHUNTER. We expect to be getting into some consensus reaching conferences sometime in the next calendar year which will provide us, we think, with a very broad scale and up-to-date evaluation of a variety of formaldehyde health effects and as necessary we will then develop whatever control options might be appropriate and not just limit ourselves to the simple question of carcinogenicity which we think in the broad universe of formaldehyde will not be the key thing.

Senator GORTON. Would you give us a brief report on OTS activity since your confirmation, on the regulation of CFS, the more prevalent use of asbestos and solvents?

Dr. TODHUNTER. On PCB's we have done two major things, one, as you know, we have been responding to a scheduled court order for reproposal of the parts of the PCB regulations that were turned down, stayed and remanded to the Agency. We are currently on schedule with that. Those parts have to do with use in electrical systems, an enclosed production rule and subsequently what we refer to a part 3 which is an actual finding of where there might in fact be a de minimus sort of usage of PCB. That is on schedule. The electrical systems rule is due out back to red border this month. The incidental manufacture rule is supposed to be back out in October and the part 3 will be addressed later in the fall, according to the court schedule.

We also proposed earlier a rule which would extend the retrofilling deadline for certain railroad transformers which are used in self-propelled passenger cars. This was as a result of a petition received from CEPTA, which is a public transportation authority in the northeast, which came in on their own particular behalf but also was subscribed to by a variety of public transportation authorities in the northeast.

It turns out that despite efforts to find an alternative dielectric fuel in these self-propelled cars which have a safe-flash point because, I must point out the transformer of a particular restricted configuration sits actually underneath the passenger compartment

and if there is a fire it is not out in the engine but in the passenger compartment, we felt it appropriate to extend the deadline and that we have done.

Earlier we also took action at the program level to recommend against the landfilling of PCB capacitors.

Senator GORTON. Do you want to go on to CFC.

Dr. TODHUNTER. In CFC, we have proposed, with the exception of spinerette solvents—solvents used to clean the little spinerettes that are used to weave nylon and other synthetic fibers. It turned out in the judgment of the Agency there was not an alternative that was acceptable and since this was a miniscule fraction of CFC usage, we felt it did not have a significant environmental impact.

Senator GORTON. Asbestos.

Dr. TODHUNTER. In asbestos, as I mentioned in my testimony, we have issued the final asbestos in schooling reporting and inspection rule. We have issued the rule requiring reporting for manufacturers, importers and processors of asbestos and we have initiated the formation of the Federal asbestos task force which involves ourselves, CPSC and OSHA. We initiated the task force since we felt asbestos is a material which has an industrial cycle in life, it would not be an effective way to approach asbestos if we who had only one piece of the asbestos' commercial cycle took it on by ourselves. So we invited our sister agencies to join in with us.

We expected that some of the information coming in from the asbestos to the reporting rule will be used to support the asbestos task force. We will be looking at currently nonregulated uses of asbestos and trying to identify any areas where further controls may be appropriate.

Senator GORTON. Solvents.

Dr. TODHUNTER. Solvents. The Agency under the Toxic Integration Office in my shop has prepared some reviews of solvents. Some of these have gone back out to the Office of Research and Development, to the Science Advisory Board for comment on the health effects documents. The Science Advisory Board found some of the health effects documents generally useful and commented on them. They will be coming out back for more review.

Senator GORTON. Senator Baucus.

Senator BAUCUS. Dr. Todhunter, as you know doubt have guessed, we have statements from other witnesses who will be testifying, one of them Dr. Clarence Davies, executive vice president of the Conservation Foundation. I don't mean to scoop him, and I apologize to him for divulging in advance his testimony, but let me direct a couple of points that he raises to you so we can get a better sense of what is going on here.

As you might guess, he addresses the question of negotiated voluntary testing agreement and basically says it is possible this approach can be made to work, but he has asked various questions that come to his mind and the mind of his organization. The first is: Are there safeguards to assure that the voluntary testing procedures will actually conform to the standards that might reasonably have been imposed had section 4 rules been written?

Will you answer that, please?

Dr. TODHUNTER. The standards they will be expected to conform to will be standards of doing laboratory practice which we will invoke in prior case.

Senator BAUCUS. I don't know if that is a satisfactory response or not.

Dr. TODHUNTER. The standards were promulgated by various agencies. We currently use the FTA, GLP, although we are in the process of developing some additional GLP of our own to confer effects that FDA has not been particularly concerned with. They were developed in response to some of the problems that occurred with commercial testing laboratories early in the seventies.

Senator BAUCUS. I wonder if you can answer by saying yes or no.

Dr. TODHUNTER. Yes.

Senator BAUCUS. Standards under voluntary testing will be the standards?

Dr. TODHUNTER. Oh, no.

Senator BAUCUS. Will the test results and the details of the tests be disclosed publicly, as would be the case if the tests had been performed under a TSCA testing rule?

Dr. TODHUNTER. We will not accept a negotiated testing agreement that will not allow us to make full test disclosure of the test data.

Senator BAUCUS. Will they be the same?

Dr. TODHUNTER. Certainly.

Senator BAUCUS. The test results and details will be disclosed as would be the case otherwise under TSCA?

Dr. TODHUNTER. Certainly.

Senator BAUCUS. There is no doubt about that?

Dr. TODHUNTER. Not in my mind.

Senator BAUCUS. He then turns to the premanufacture notification process and suggests that the major problem has been that the health and safety data submitted with the notifications has simply not been adequate to determine whether the new chemical may pose an unreasonable risk.

Let me read one paragraph of his statement:

Of the 659 PMNs submitted in 1981, none contained test data on chronic health effects. Only 15 percent contained data on mutagenicity screens, a quick and inexpensive test to indicate whether the chemical might cause chronic effects. Less than half the notices contained data on acute health effects, such as skin or eye irritation, and only ten percent contained any data on environmental effects. Forty-three percent of the notices contained no toxicity data at all.

What is your response to that?

Dr. TODHUNTER. Well, it is very easy to look at a chemical without actually being familiar with what goes on in safety evaluation, since I presume Dr. Davies must not be, and say we have to have this, we have to have the other to make some reasonable cut at what the chemical may or may not do. I don't think anybody in this business of trying to generate a public health program with commercial chemicals internationally is advocating the idea that very early in the development of the chemical one has to go for full chronic and things like that. Even the European community under the sixth amendment is not based on chronic toxicity but to the physical properties. It has one thing related to chronic and that is

the Ames test. The Ames test is thrown in because it is a cheap way of picking up some reaction to it.

Now, what we do normally receive with PMN is some information on physical chemical properties and sometimes we do get some Ames test in. The first thing we do is we sit down and we compare this chemical to other similar chemicals. And I need to point out that in all 1,500 notices that we have received, we have not seen any new chemistry except one time. The one time that we saw new chemistry—in other words, we did not have comparable materials to make assessment, we realized and recognized that, went back to manufacturers and said, you want to make 20 pounds of this thing, that is fine but if you make 60 we want to hear about it again and want some additional information because we don't know how to evaluate this. I will also point out that in some cases our analysis done by our staff has pointed out errors in physical property measurements made by submitters.

Senator BAUCUS. He also comments on the proposed exemption for chemicals from the PMN requirements and suggests that the basic principle of exemptions makes sense for various reasons and he feels that the exemptions of chemicals manufactured in quantities of less than 1,000 kilograms per year is probably sound, but then goes on to question the exemption for chemicals manufactured in quantities of less than 10,000 kilograms, the suggestion that it is too high. His reasons are that there is no good way to ascertain exactly what the right volume-of-production cutoff should be, and 10,000 kilos is 10 times the production volume allowed to be exempted under the new chemical regulatory scheme of the European Economic Community, and under the EEC directive, when annual production of a chemical reaches 10,000 kilos, the manufacturer may be required to conduct a second tier of tests, including a fertility study, a subchronic toxicity study and a variety of ecotoxicology studies.

What is your reaction to the 10,000 kilo exemption?

Dr. TODHUNTER. It is not directly comparable to what is done under EEC because the EEC's sixth amendment is not a premanufacture law such as TSCA is, it is a marketing statute so one does not report under the sixth amendment until in fact one has sales receipts for 1,000 metric tons per year. Up to that point, you simply do nothing. Under our current program, one in fact reports anything in any volume that one intends to manufacture. Now this does reach pretty far back into some pilot activities and some R. & D. activities. In fact, we find really it does seem that not more than about 40 percent of what comes through our program actually does get manufactured—a lot of good intentions out there apparently—and no more than 30 percent of the total, not 30 of the 40 but 30 of the what we see in fact gets folded at some point, commercialized. Because of that, I don't think one can compare our thousand metric ton cutoff which is our first level of exemption for low volume with the European metric ton and I don't think you can compare our 10,000 with whatever the Europeans do because between 1,000 and 10,000 pounds, what we will be requiring—and again this is something which is out in the Federal Register and we are soliciting comments—we will be requiring that "qualified expert" to evaluate the conditions of usage reported on it, made

some initial determination, the Agency itself would take its 14 days.

One of the reasons I would like to point out where this 14 days came from is because there have been some questions, "Why did you select 14 days?" phrased informally by various of our friends in the press. The reason is that the way the present PMN program presently works is that when a chemical comes in, it is assigned to a team of chemical engineers and toxicologists who evaluate both the condition of use and the chemical itself and the first decision point in the system is that 14 days. In the 14 days, we make an initial cut whether to put it aside on the shelf because it is clearly nontoxic or to go further with more evaluation requesting information or whatever. So there is a lot that we get in, a lot of polymers that are not toxic, some of these low-volume things, very limited exposure, so that by 14 days we already know.

What we are really doing is proposing a system that will allow us to take advantage of appraisal of things that we do.

Senator BAUCUS. A recent 2-day symposium conducted by EPA in May reviewed new health effects information on PCB exposure. I understand two industries commissioned studies to review this.

What new information did these studies yield and how did EPA intend to use it?

Dr. TODHUNTER. I have not seen the published reports from the symposium, they won't be available until early next year. It is my informal understanding that we do not agree at staff level with all of the points raised by the industry.

Senator BAUCUS. What is the nature of this agreement?

Dr. TODHUNTER. I do not know.

Senator BAUCUS. Informally, the staff has not told you the major disagreement?

Dr. TODHUNTER. As I say, this is what I hear informally from my program director. We don't see eye to eye but I don't know what the points of disagreement are. Really at this point we have not seen the published reports and have not had that formally evaluated.

Senator BAUCUS. Was other information on PCB exposure evaluated under the study commissioned by Ames Electric?

Dr. TODHUNTER. There were presenters from other areas. We had presenters from Europe and also from our CDC that presented some of their own work.

Senator BAUCUS. When was that information evaluated?

Dr. TODHUNTER. Most of it would have been evaluated through the process of presenting it at the symposium and then having those things published. That is the normal mechanism for scientific exposition of information.

Senator BAUCUS. Thank you.

Senator GORTON. We will have a few additional questions to submit to you in writing, but we appreciate your long and interesting testimony. Thank you very much.

Dr. Davies and Ms. Warren, we will hear you now.

We will include all of your testimony in the record. If you will summarize, that will be helpful.

STATEMENTS OF DR. J. CLARENCE DAVIES, EXECUTIVE VICE PRESIDENT, CONSERVATION FOUNDATION, AND JACQUELINE M. WARREN, NATURAL RESOURCES DEFENSE COUNCIL

Dr. DAVIES. Let me briefly summarize my points and maybe respond a little bit to the responses that Senator Baucus received.

In terms of negotiated testing agreements, I thought Dr. Todhunter's responses encouraging, particularly on disclosure, because that has not been the information we have gotten—either we misunderstood or there has been a change. Our understanding was that summaries of the results of the tests would be made available rather than the test data itself and I am very pleased if that is wrong.

We do still have some concerns about what happens if the test is not performed well and promptly.

Yes, it is difficult to enforce testing but rules are enforceable and there are penalties if people do not comply with rules.

Our concern is—and this is not something that we feel would generally happen—but it is conceivable that it would be in the interest of a manufacturer to agree to do the testing and then for any number of reasons not to. Then under the voluntary and negotiated agreement in fact there will be no penalty.

I have much more difficulty with the response of Dr. Todhunter about the premanufacture notification data. As he indicated, the general policy of the Office of Toxic Substances has been in effect to rely primarily on structure activity relationships to determine the toxicity of the new chemicals for which notices are received. That is not a change in policy, that has been true for the last 4 years. And we were just as critical of the old administration on that score as we are of the current administration. I, myself, am not a scientist, but I do not know of any good toxicologist who will tell you that, at least for many chemicals, you can determine toxicity from the structure of the chemicals. Structure-activity relationship is a very primitive and undeveloped area, and in fact toxicologists are just beginning to learn how to predict a chemical's effect from its structure.

There are any number of examples of chemicals whose structure are closely related and whose toxic effects are in fact quite different. So, in short, there is no good substitute for having test data, and structure activity relationships are not adequate substitutes for testing.

Let me turn to the exemption policy and some of the criticisms that we have or some of the problems that we foresee.

There are some things we agree with. We do agree in principle with the notion that you can exempt some categories of chemicals and not worry too much about incurring unreasonable risk. We believe that to exempt chemicals manufactured in quantities of less than 1,000 kilos per year is probably a sound policy.

We do have a problem with the 10,000 kilogram exemption. We also have a problem with the blanket exemption of site-limited intermediates. Many site-limited intermediates are highly toxic and if not properly handled can cause severe health risks. The case of BCME at Rohm and Haas is probably the best documented example. Furthermore, the exemption proposal provides a major incen-

tive for companies not to conduct toxicological tests on chemicals subject to exemption by assuming that they are exempt unless test data indicate the contrary. So the manufacturer has nothing to gain by doing testing, he can only lose.

Our belief is that the site-limited intermediate exemption should be limited to specific categories of intermediates designated by EPA. Other intermediates could be exempted if toxicological testing indicated they would not pose an unreasonable risk.

We have some problems with the qualified expert notion. The lack of definition is troublesome because in a lot of the cases of the smaller manufacturers you may have a plant engineer certifying as to the toxicological properties of chemicals. I am not too worried about DuPont or Monsanto in terms of qualified experts, but those are not where the worst problems tend to be. You are not likely to have eminent toxicological experts review any chemicals in a small manufacturing operation.

The notion of an audit program to check on the qualified expert's report, as I say in my written statement, strikes me as truly ridiculous. This is going to be a written report. If it is going to be audited it has to be written. The cost to industry of EPA receiving these reports is the cost of an envelope and a 20 cent stamp. If EPA wants to see the quality of these reports and know where they are being done, the easiest way is to require that the industry submit it to the Agency. That seems to me fairly straightforward.

We have not had time to review the polymer exemptions in any detail. We just got a copy of that yesterday. It is 40 small printed pages. In terms of the general approach, we do believe there are broad categories of polymers which can safely exempted.

We are concerned about the lack of any penalty attached to the exemption policy. The policy apparently does not call for any penalty to be applied to a manufacturer who considers a chemical exempt when in fact a PMN should have been submitted. As I read the policy, this is specifically applicable in the case of the manufacturer who wilfully or negligently categorized the chemical as being exempt when it should not be, and it seems to me that is not a sensible policy.

In terms of international harmonization, I would like to comment on the statement in Dr. Todhunter's testimony, that the exemption policy brings TSCA closer to the European regulatory system. I think in fact this is only half true. The European system covers fewer types of chemicals than TSCA. However, it is stronger with respect to data that must be submitted for new chemicals, and in fact the sixth amendment contains a long list of the kinds of data which are required to be submitted for new chemicals and there are further lists of types of data required to be submitted as chemical production volume increases. There is, obviously, a close relationship between the types of chemicals covered and the types of data required to be submitted.

Under the European system fewer chemicals are covered because more testing is required. It would be unfeasible to require the amount of testing required under the European system to the number of chemicals currently covered under TSCA.

What I read the EPA exemption policy to do is adopt the weaker part of the European system and ignore the part which from the

health and safety standpoint is stronger than the U.S. system. They have limited the number of chemicals covered but not done the other half of the job which is to increase the data requirement on those chemicals that are covered.

It seems to me that the proposed exemption policy in effect is half a policy, and the other half should be an attempt to remedy the weakness of the data submitted on new chemicals. Thank you.

Senator GORTON. Thank you.

Ms. Warren, we will go to you. We will include your full statement in the record so we would appreciate your summarizing.

STATEMENT OF JACQUELINE M. WARREN

Ms. WARREN. I wanted to speak to the three principal question areas that were in the letter of invitation.

The first involves voluntary testing under section 4. We have been involved with the voluntary negotiation process because it was an NRDC lawsuit that got the Agency on a schedule to address the first 37 chemicals that the Inter-Agency Testing Committee recommended to them as priority candidates for testing.

The whole point of section 4(e) is to identify for EPA those chemicals which because of high volume, wide usage, or structural similarity to known bad chemicals, ought to be the subjects of testing first. The interagency group that was set up by the statute consists of experts from scientific and regulatory agencies around the Government. Section 4(e) is an action-forcing provision. The agency is given 1 year from the date of receipt of the recommendation to make a decision whether testing ought to commence or whether testing is not necessary. Then the statute says: If testing is necessary, it shall be done by rule. And although Dr. Todhunter said here that the opportunities for public involvement and the standards applied are all the same as if done by rule, we disagree with that.

One point I want to clarify: Section 12(b)(1) specifically states if a chemical is under test under section 4, that there is to be notification of foreign governments about that fact. It is the second section of section 12(b) which says also that chemicals regulated under sections 5, 6, and 7 are subjects of notification. That is the kind of provision that doesn't become operative if the matter is the subject of negotiation rather than of a rule.

We are involved, to the extent we have been informed by EPA that they are talking to this or that industry group, to work out a testing negotiation. The testing proposals have not been published in the Federal Register.

My most recent involvement was a letter dated July 6 which arrived July 15 inviting us to a meeting to discuss recent ITC recommendations on the 12th and 13th. Since the letter didn't arrive until the 15th, there was no possibility for us to become involved. There was no notice in the Federal Register. Thus, there was no opportunity to suggest changes in the protocols. In fact, if we really disagreed with EPA's final determination as to what tests were appropriate, acting by rule offers an opportunity to go to court and have an independent, objective third party decide whether the Agency's determination on its own record was appropriate or not.

That is what the law provides. As to any enforceable requirements such as good laboratory practice—I may be wrong, but it seems to me that good laboratory requirements are not mandatory. They have not formally been promulgated so they are not mandatory.

I personally favor companies doing their own testing. I think they should do it and the policy statement in the beginning of the statute states that data should be developed by the companies that produce the chemicals.

At the same time we are talking about the highest priority candidates for testing, which a special group of experts has recommended that EPA address in an expeditious way. By doing it entirely voluntarily, what we will be left with, if it doesn't work out the way EPA anticipates, is having to do it by rule many years down the road. The Agency has yet to promulgate a single testing rule although one or two have been proposed over the past 2 years. And there seem to be no present plans to finalize those rules.

What we would like to see is negotiation with the industry for what tests ought to be conducted, but then encapsulating it within a rule that will put into play all of those requirements such as public involvement, enforceability, and deadlines, that were envisioned when the statute was written.

We have not seen any indication that that is going to be the case. Although there is a voluntary negotiation process being developed at present, which perhaps is enforceable the way a contract is enforceable, I don't believe that is the kind of agreement being made. I think it remains essentially a voluntary approach.

The same kind of problem is exacerbated when you begin to look at voluntary advisories for chemicals that should be controlled under section 6. I delineated in my testimony all of the statutory provisions that won't come into play if the Agency opts for voluntary control measures once they have determined that something poses an unreasonable risk.

Dr. Todhunter said that that isn't what they intend to do, and I will accept his word for that, but I did want to point out that if such a change were made it will effectively repeal TSUA. As an inherently regulatory statute with every provision referring to other provisions that are supposed to be implemented by rule, if actions are not taken by rule, none of these things become operative, including those providing for judicial review, citizens petitions for issuance, amendment or repeal of a rule, citizen suits to enforce a rule, notification of foreign governments of substances addressed by rule, and so forth.

I made a statement in my written testimony that I would rather you repeal the statute than have EPA do it administratively, and I feel that very strongly.

With respect to premanufacture exemptions, I share many of the same concerns that Dr. Davies articulated in his testimony. I have serious concerns about the qualified expert. While in the plane coming here, I was thinking about the absence of any guidelines for what the qualified expert's credentials should be, or how the qualified expert's review is to be conducted, I was thinking to myself that I'm glad airline pilots are not licensed in that way. There is no guarantee that the person who is going to look at a chemical is going to have the expertise to make an initial judgment

about potential hazard. I view such a broad delegation to industry of EPA's initial authority to screen new chemicals to be something that really violates the spirit if not the letter of the statute.

There is provision for exemption in TSUA and I think that exemptions are appropriate in some cases. They are, however, supposed to be granted by rule and only after a finding that the chemical or the category of chemicals will not pose an unreasonable risk. I don't see how EPA can make the finding that unknown chemicals of unknown toxicity will not pose any unreasonable risk.

We were involved in some of the negotiations to develop this proposal and I wanted EPA to require that it be able to see the basis for the qualified experts' determination. If that determination is to be written down and put in the company's files, it ought to be submitted to EPA. The way the proposal has been issued, the Agency now has 14 days to do what it presently has 90 or 180 days to do. They are not going to get the benefit of any hints or tips from what the qualified experts looked at to tell which chemicals looked structurally similar and so forth.

We have been involved in a number of lawsuits involving Agency efforts to regulate substances on the basis of similarity of structure. In these cases, EPA's decisions were being challenged because there could be differences in structure which make all the difference whether the substance is toxic or not.

We are also concerned with site-limited intermediates for many of the reasons Dr. Davies indicated. I think the Agency has a responsibility to look at new chemicals in the first instance unless they are quite certain there will not be an unreasonable risk. I venture to guess that the number of chemicals for which that finding can be made with certainty is far smaller than 50 percent. It is somewhat ironic that the Europeans now have in effect a system that requires the generation of data on many new chemicals. This applies to companies who manufacture for sale in Europe. American companies manufacturing and selling in Europe have got to do more than they have to do for sale in the domestic market. I will say that one unintended side-effect of the institution of the EEC system is that companies which manufacture the chemical abroad first are going to have to supply the data that they generated to meet the EEC requirements when they want to market in the United States, so we will get some benefits from it.

I think if this country is going to have to harmonize with the EEC and OECD, and that TSCA ought to be amended to put in the mandatory minimum data testing requirements for new chemicals.

I would like to say one last word about the general approach to scientific issues at EPA these days. I have been involved in the formaldehyde controversy. Dr. Todhunter stated his concern he didn't want to have to consider only carcinogenicity. Sections 4(e) and 4(f) focus on the three adverse health effects of greatest concern to people which are carcinogenicity, teratogenicity and mutagenicity—

Senator GORTON. Are you almost through?

Ms. WARREN. Yes; I am.

There is disparity between the regulatory agencies today where one agency looking at precisely the same data as another says it is not a significant risk while the other agency does not agree. For

that reason, I would urge you to exercise your oversight responsibility to prompt the EPA to give good justification for the determinations it makes, and to assure that its science is as unpolitical as possible. Theoretically two agencies should not come to completely contrary determinations on the same chemical on the same data base.

Senator GORTON. Senator Baucus.

Senator BAUCUS. Thank you very much, Mr. Chairman.

Dr. Davies and Ms. Warren, often it is smaller businesses that complain about uniform rules as they apply to all firms in the industry. The larger firms have an easier time absorbing some of the costs and reacting to rulemaking whereas smaller firms have a more difficult time, they can't spread out the cost as much and they are not as diversified and sometimes can't pass on the cost as easily as can larger firms.

I suppose a good argument can be made on the part of the smaller chemical firms that the voluntary testing procedures as well as the exemptions are necessary, and it seems clear to me that smaller firms do have a more difficult time as a rule than do larger firms.

Isn't EPA doing the right thing here with its voluntary testing procedure adapting to smaller firms sizable exemption, addressing very legitimate problems that smaller firms face?

Dr. DAVIES. In terms of voluntary testing, it is fairly unlikely that small firms are going to be involved in testing, at least for the ITC chemicals. We are talking about fairly——

Senator BAUCUS. What about exemptions?

Dr. DAVIES. The impact on small business is an important part of the exemption policy and that is one of the reasons the 1000 kilogram exemption makes sense.

Senator BAUCUS. What about halfway between 1,000 and 10,000?

Dr. DAVIES. As I commented in my testimony, there is no totally rational way to arrive at the magical number which is the cutoff point.

Senator BAUCUS. Mr. Scott talks about 10,000 pounds. Why don't we say 5,000 kilos?

Dr. DAVIES. I think it is important to stress that there have been a lot of studies of the impact of the PMN requirement on small businesses although there are still very mixed opinions on the subject. I think especially if there is a 1,000-kilo exemption, it is unlikely that the burden of submitting notifications is going to have a significant adverse impact on small business.

Ms. WARREN. I want to add one thing. The company that manufactured kepone, although it is a pesticide and governed under a different statute, it was a small company but its product caused serious injuries to people who worked there. The size of the company isn't the only factor.

Senator BAUCUS. I agree.

Ms. WARREN. It is a factor but it can't be the only one.

Senator BAUCUS. Thank you very much.

Senator GORTON. Doctor, the development of the four agreements negotiated so far, to what extent did either of your organizations participate?

Ms. WARREN. We participated in some discussions on the first two, the phthalate esters and chlorinated paraffins, in some preliminary sessions that EPA called scoping sessions but are not actual negotiations. They are for raising issues and asking for information.

I don't know of any other public interest or environmental health or any other nonindustry organization that has participated in them at all. We were not participants in the negotiations.

Dr. DAVIES. We did not participate. We do not have toxicological experts on our staff. The Conservation Foundation is concerned broadly with environmental policy.

Senator GORTON. Is that lack of expertise the primary reason?

Dr. DAVIES. It is a major reason, yes.

Senator GORTON. Ms. Warren, you stated in your testimony that although EPA's affidavit to the court in *NRDC v. Costle* says that the agency is complying with court ordered schedules for test rules development, events over the past year suggest to the contrary.

Could you amplify on that? In what way has EPA failed to comply and what have you done about it?

Ms. WARREN. So far we have grumbled about it and written letters. Our main concern is that they have not complied with the purpose of a 1-year deadline to initiate the issuance of a testing rule. That purpose is completely defeated if the rule is never promulgated and the testing never goes into effect.

There presently are two or three testing rules that were proposed that have never gone final. The Agency has issued advance notices of proposed rulemaking, which they feel satisfies their obligation under the statute, but we disagree with that. They have also made decisions not to require testing because the tests schemes are being negotiated. To the extent that rules are issued but never become final, the objective of the provision which is to get the testing going is defeated. Advance notices of proposed rulemaking are not binding on the Agency, so we don't consider them as satisfying the statutory obligation. We may be initiating a lawsuit on that.

Senator GORTON. I would like to thank both of you for a great deal of help and for your comments to Dr. Todhunter's testimony.

Our second and last panel this afternoon will consist of Mr. Hurst and Mr. Scott.

STATEMENTS OF E. HAMILTON HURST, VICE PRESIDENT, ENVIRONMENT AND HEALTH, NALCO CHEMICAL CO., REPRESENTING CHEMICAL MANUFACTURERS ASSOCIATION; AND MICHAEL J. SCOTT, GENERAL COUNSEL, MOONEY CHEMICALS, INC.

Senator GORTON. Mr. Hurst, you may proceed first. Again, your entire statement will be included in the record. We will appreciate your summarizing it.

Mr. HURST. Good afternoon, Mr. Chairman and members of the staff. My name is Hamilton Hurst. I am vice president of Environment and Health and Safety at Nalco Chemical Co. At Nalco I have the responsibility for compliance with TSCA for our company as well as for other matters dealing with health and safety within our company. I also happen to be the current chairman of the CMA committee dealing with the Toxic Substances Control Act.

I am pleased to be here today to speak on behalf of CMA about the implementation of TSCA. Our industry is particularly interested in the implementation of TSCA regulations proposed under the statute which have far-reaching effects on our industry. TSCA is designed to regulate those chemicals which pose unreasonable risk to human health and the environment. However, the impact of the law can effect all chemicals manufactured, processed, distributed, or used in the United States.

CMA actively supports TSCA in its goal of preventing and in controlling unreasonable risk to health and environment. Let me stress that we continue to support a timely and reasonable implementation of the act in accordance with that objective.

In my remarks today I will comment on the following areas of importance to us, premanufacture notification and the negotiated testing and the impact of the international toxic substances regulations.

Let's deal first with the premanufacture notification.

PMN is set up by section 5 of TSCA and is the process that is used in the act for the Agency to review new chemicals. The act requires that potential manufacture provide information in his possession on the new chemical. While the Agency has proposed detailed regulations on this process, the rules have never been finalized. However, the statute itself clearly outlines the process and for the past 3 years the system has worked well using the statutory process.

During this 3-year period some 1,500 notices had been submitted and although there have been some questions by some on the adequacy of the data that has been submitted, the Agency has had to request additional information in only approximately 50 cases, just 3 percent of the total PMN submitted. I think this in itself indicates that the present system is working well. Being able to process 97 percent of the PMN's without asking for additional information is indicative of a highly efficient system by any set of standards. Since so many of the PMN chemicals are inherently low risk, the Agency is able to complete its review of over 50 percent of these cases within the first 2 weeks. Even though the Agency may have decided at an earlier date to not take action on these low-risk chemicals, the PMN chemical must wait its full 90 days before it can be manufactured.

Based on experience with the PMN review process, we believe that the process can be streamlined by exempting some chemicals from full-scale reviews without any risk to public or to the environment. Exempting low-risk chemicals from full PMN review will allow the Agency to make more efficient use of its resources by focusing on those chemicals which require more indepth review.

Furthermore, exempting low-risk chemicals will remove financial and time delay burdens which discourages new chemical innovation. This helps the EPA meet the congressional requirement that TSCA not impede innovation. For these reasons we petitioned EPA to exempt certain low-risk chemical polymers, site-limited intermediates and low-volume chemicals.

One of the major differences between what we have proposed at CMA and what has been the case with the European law is that we have established some safeguards so that not all chemicals will be

exempted. The European law, for instance, allows an exemption for some 2,000 pounds of material, but there are no qualifications at all to that, any product less than 2,000 pounds will be exempt, any intermediate will be exempt. In our case, high-risk chemicals would not be eligible for the exemption as proposed. We would not have intermediates that will leave the manufacturing site eligible for an exemption. Certain polymers will not be eligible for an exemption. In our case we suggest that the EPA be notified by anyone seeking the exemption so that EPA is aware of the chemical.

In addition, the industry will use the qualified expert to evaluate the proposed chemical to insure it meets the qualifications criteria. The exempted chemicals can be manufactured only by the person submitting the exemption notice. In fact, EPA upon their review, which they will have the opportunity to do, will be empowered to revoke the exemption should the chemicals not meet the requirement of the exemptions.

The exemptions requested will streamline the process by reducing cost for both agency and industry, lessening impact on innovation and most importantly not allowing chemicals to escape review prior to manufacture. Our membership will be reviewing in detail the Agency's proposed exemption policy issued just last week and will comment in support of that proposal. We believe the proposed reaction on the part of the agency is appropriate use of its authority under TSCA and will afford major benefit to the public, EPA and the industry.

Turning now to the negotiated testing, the chemical industry supports EPA use of negotiated testing programs to provide an alternative to formal testing rules for chemicals. We believe that these negotiated testing programs have advantages that have been demonstrated by several programs already in place and working. And negotiated programs may be developed quickly in a year or less instead of the many years that formal rulemaking might require. Thus test data can be obtained much faster for use in safety programs and for regulatory decisionmaking.

Negotiated testing programs have developed from shared views of many parties encourage the use of good science. Agency and non-government experts can work together to develop the test program that uses state of the art methods. This approach also allows all interested parties an opportunity to voice their views to EPA before agreement is reached and finalized on the test program.

The negotiated test program contains the same basic ingredients that are characteristic of testing programs developed by formal rulemaking. These include agreement on the test protocol, the use of good laboratory practice and target dates for starting and completing the studies. These agreements are resource intensive and having made these investments it is unlikely that the program will not be completed. The motivation for doing so is not just to maintain the company's credibility for living up to its commitment to a government or consortium of companies that may be involved in the sponsoring of test programs, but it is also the recognition that if the negotiated program does not proceed that the agency can and we will expect will require a formal testing rule under section 4.

We realize negotiated testing programs will not completely replace formal rulemaking. Test rules may be necessary if no agree-

ment can be reached in the negotiated program for the various chemicals involved.

We cannot talk about TSCA without commenting on the international programs being developed to control chemical risk. While EPA is well on its way toward implementing TSCA, many of the remaining developed countries are playing catchup with the United States in regulating toxic substances. Such laws in undeveloped countries either do not exist or are dwarfed by TSCA. Because of differing individual national priorities, legal systems and public concerns, these laws vary in legislative approach, particularly in areas of notification, testing requirements, protection of trade secrets and regulating authority.

The chemical industry exported approximately \$21 billion worth of products in 1981. And we are concerned about tariff and nontariff trade barriers and we actively participate in organizations such as the OECD which strives to eliminate such barriers.

However, efforts to achieve a uniform international system for regulating chemicals face great difficulties due to widely varying national interests. Because of these difficulties in our opinion the world should not rush to adopt a uniform system based on regulatory concept from which there have been very little or no actual experience.

For example, in the PMN area such a concept is illustrated by the minimum premarketing set of data which is being discussed in the OECD discussions. The MPD is based on the newly implemented European program and there has been very little experience on that to date. The MPD not only conflicts with TSCA in that it mandates a predetermined set of tests that apply to all chemicals. There are significant questions in how MPD will be implemented on a scientific and practical basis. As was indicated in Dr. Davies' testimony, it is not just a problem of where the commas are placed in the wording of the agreement, but there are some significant questions here as to how that would impact the law.

CMA believes that the experience obtained during the recent intergovernmental negotiations on MPD indicates that the establishment of one uniform regulatory system for toxic chemicals internationally is clearly premature and probably unwise. We believe that the efforts of international organizations, such as the OECD, should instead be directed to harmonization activities which lead to developing an understanding of regulatory systems, the mutual acceptance of data, and the development of compatible systems.

We are pleased that the Senate is interested in the international area and the laws that are developing and how they might impact our law and our business. Over the course of 6 years the U.S. Congress carefully crafted a workable sound law in TSCA and we see no reason at this time to import a specific part of some other foreign toxic substances law, many of which are untried and new, and to simply insert these into the framework of our unique law.

Likewise, we think one should be very cautious of international agreements through organizations such as OECD would impose regulatory approaches that the U.S. Congress rejected when it wrote TSCA.

Let me summarize what I have tried to cover here today. We feel EPA has made good progress in meeting TSCA's goals and is rapid-

ly implementing the remaining sections of the act. We believe the present PMN system is working well to evaluate new chemicals. There have been adverse effects from the present PMN system on innovation, the section 5(h)(4) exemption proposal should help reduce the PMN impact on innovation. Voluntary testing is demonstrating advantages for the public, EPA and for industry and should become a useful tool to meet the needs of section 4. We believe we should be more forcefully promoting the merits of our system internationally instead of so quickly agreeing to foreign concepts.

In CMA's judgment, TSCA is a workable law and, if implemented in a fair and reasonable fashion, can provide a sound framework for regulating the health and environmental effects of chemicals. We see no need for TSCA amendments at this time.

I would like to thank you, Mr. Chairman, for the opportunity to appear before your subcommittee today and I will be happy to answer any questions you may have.

Senator GORTON. Thank you very much. We will now hear from Mr. Scott. Mr. Scott, your entire statement will be included in the record, and so, if you would summarize.

STATEMENT OF MICHAEL J. SCOTT

Mr. SCOTT. Good afternoon. My name is Michael J. Scott, and I am general counsel for Mooney Chemicals which is a small manufacture of specialty chemicals, located in Cleveland, Ohio. Today I am representing the Synthetic Organic Chemical Manufacturers Association, referred to as SOCMA. At SOCMA I am chairman of the toxic substances committee and have worked closely with the small business committee also.

SOCMA is a nonprofit trade association representing over 100 organic chemical companies, the majority of which are small companies.

I have submitted written comments for the record and I would like to summarize the five key conclusions regarding the TSCA implementation and the impact on small business.

The first is that small business is adversely and disproportionately affected by the cumulative impact of TSCA. And because of this we urge that Congress and EPA would undertake a comprehensive review of the entire and total effect of TSCA on small business, and to develop an integrated policy to minimize the effects of TSCA on small business consistent with health and environmental objectives of the act.

Premanufacturing notification requirements, the PMN, have inhibited innovation in small companies and to promulgate a final PMN exemption to greatly minimize this burden, this burden on innovation.

A consistent definition of small business is vital for small businesses and the Agency. We welcome the Agency's proposed definition of small business under the recent section 8(a) reporting rule and we would urge that this definition be used where appropriate in other reporting and recordkeeping rules.

We feel that the negotiated rulemaking and negotiated regulation between EPA and industry is a flexible and intelligent method to achieve the objectives of TSCA.

Let me expand on these conclusions where I feel appropriate. I would like to illustrate some of the characteristics of small companies and show where TSCA has impacted these.

In general, small companies produce a high number of small volume chemicals. Many of these have a short life cycle. Because of this, there is insufficient return on these chemicals to support a high PMN in cost. Extensive PMN data up front on a chemical for low-risk chemicals do not seem to have a corresponding benefit for health or the environment. Small chemical companies rely on a narrow range of technology often with cumulative experience from many years of handling, use and risk analysis for a particular line of chemicals, therefore PMN proposals that require extensive environmental and toxicological evaluations up front, according to specified protocols, in many instances merely confirm what is already known to company experts—and here I use my company, Mooney Chemical as an example. We manufacture metal combined with organic acids, and within our technical and engineering people we have over 150 years of technology experience in this particular line of chemistry. We feel we are a prudent and responsible company and with this type of experience we certainly generate adequate data, adequate for reasonable PMN review and adequate and consistent with the volume and use of these chemicals.

Finally, small chemical companies tend to rely on quickly responding and innovating for their customers' needs and obviously the PMN, the wait [delay] and paperwork has unnecessarily blunted any competitive edge that we have.

I would note that EPA and Congress have been sensitive to the issue of small business and have recently taken commendable action. However, we feel more is needed. We would like to urge and recommend that Congress and EPA undertake a comprehensive and systematic review of TSCA and small business. We would urge that this review and analysis be used to minimize the burdens on small business where this is consistent with the health and environmental goals of TSCA. I have cited two reports in my written comments which support conclusions. I feel this should be an approach the Agency is looking at which would minimize the burden on small business. Again, the recently proposed exemption is a welcome development in a step toward restoring the balance for the introduction of new chemicals. The final exemption rule along these lines would greatly minimize the burden. We feel a tiered approach, as has been adopted in the proposed rule, would be in the best interest of improving the innovation.

In essence, the PMN exemption permits the manufacture and sale of certain low-volume chemicals manufactured at one site with a risk assessment—and I would say that for our particular chemicals, Mooney can perform this type of risk assessment—where this risk assessment would indicate that no serious health or environment effects would result.

We have continuously urged EPA to promulgate a small business definition under section 8(a) reporting rules. The recently proposed rule is a long awaited first step in implementing the congressional

intent to minimize the burdens on small business where this is consistent with the goals of TSCA. In the past the Agency has used a rule-by-rule definition of small business. Now we feel that we have a legitimate definition and a rationale of record that we can use in addressing the Agency and the Agency can use in addressing the problems of small companies.

We would urge that this section 8(a) definition of small business be applied in other section 8 reporting and recordkeeping rules where this is appropriate.

My final comments pertain to negotiated rulemaking. I know for Mooney, and other small companies, I speak strongly when I say that negotiated rulemaking will allow the smaller companies to enter into and become involved in the rulemaking process. The formal rulemaking procedure can be time consuming and expensive if not intimidating for small business and I feel that negotiated rulemaking where positions can be discussed and exchanged in an informal manner will be a welcomed development.

On this point, I would like to add that small companies are particularly concerned with the confidential information that they have and that they feel is necessary to give to the Agency to tell the Agency in these rulemaking procedures—and this is another reason I think that a negotiated rulemaking where there are considerations for confidential business information will be helpful.

In summary, I have pointed out the need for EPA to adopt an integrated statute-wide approach to implementing TSCA which balances the cumulative impact on small business with the goals of the act. I would like to say that Mooney Chemicals as a small business feels we are competent to take advantage of new fresh air that EPA has come out with in their exemption proposal and we feel that this will help innovation and balance the health and environmental aspects of TSCA.

I thank you, Mr. Chairman, and welcome any questions.

Senator GORTON. Thank you, Mr. Scott.

Your written statement includes the suggestion that personnel at companies which are members of your association would be capable of undertaking the reviews necessary for certifying that a new chemical qualifies for one of EPA's proposed exemptions in the PMN process. But elsewhere in your testimony you state that small companies, to a large degree, lack the in-house technical staff to generate extensive toxicological data.

How are those two comments consistent?

Mr. SCOTT. I think the comment as to the large administrative and technical support staff, it is just that, it is geared toward reporting and recordkeeping. I know that for our company with out technical director and research people, in all the companies I have ever come in contact with, we do have more technical expertise than—I think I heard the comment earlier—of the plant engineer. We have a plant engineer, but in the risk assessment for the smaller companies that are technically oriented, I am sure they will have a technical director and other research people on staff whose time I feel would be misspent in reporting and recordkeeping. I think that was the gist of the comment.

Senator GORTON. Mr. Hurst, you stated in your testimony that allegations of significant adverse reactions under section 8(c) serve

the purpose of indicating a potential problem which requires further investigation.

With those circumstances, why does CMA seem to object to automatic reporting of these allegations in order to enable EPA to identify a pattern of problems warranting such investigations?

Mr. HURST. Our concern with the proposed rule that was put out more than a year ago under 8(c) is that it went further than what the statutory authorities in the act presumed.

We were concerned that the allegations could include any number of verbal types of allegations, any number of things that would not be substantiated and therefore we question the value of many of the allegations that might be present and whether or not it was worthy of an automatic type of reporting that would be required.

We think 8(c) has a very valuable role to play in the overall information gathering system within TSCA. The information is available to the Agency when they have reason to seek the information but we don't believe that it is something that ought to be set up on an automatic reporting basis. If the information indicates a substantial risk, the company is obligated under section 8(e) to report the information to the EPA.

Senator GORTON. Is industry in general testing more chemicals or testing chemicals more thoroughly now than it was before TSCA was enacted?

Mr. HURST. I am not familiar with any particular set of numbers that I can cite you to answer that question, but I know in our case in our company we are. I have to believe that any number of other companies are in the same situation as we work our way in the business sense to fulfill the obligations not just for TSCA but other requirements that the public wants and need information.

Senator GORTON. What is the reason, then, that we had testimony earlier this afternoon that PMN submitters are including only limited health and environmental effects data with their submission?

Mr. HURST. I think that comes back, Senator, to the question of where in the process the PMN is being submitted. The law says before we manufacture a chemical for commercial purposes. We do not find in practice that this is necessarily the case. We find, for instance, that many of our customers require that we go through a PMN even though we are not really at the point where we have a full intention to manufacture the material, we are still in R&D.

Also, I think you will find that as we look at many of the chemicals, and I think this has been in the testimony of myself and Mr. Scott and Dr. Todhunter, so many of the chemicals that are being developed that are new, the definition of new is based on an inventory listing, that these materials are basically just minor modifications of a family or class of chemicals that have been worked with for any number of years. I think that a little bit of, perhaps, what Mr. Scott is saying, there is a lot of expertise that exists that says if I simply change sodium ion or a calcium ion that I have not changed the toxicological properties of the chemical and therefore I know enough about the material that I don't feel I need to do additional testing.

I think this explains a lot of reasons why you do not see additional data come through. You are not seeing new chemistry and you are not seeing chemistry that we don't know something about and it is a basis, in a way, for the exemption program we have been suggesting to the Agency and we are pleased to see they are coming forward with.

Senator GORTON. You partly answered this last question in dealing with that one. But each of you has testified that money, efforts, et cetera, involving developing of PMN to be submitted is significant. Mr. Scott mentioned the figure of \$20,000 as an average cost. Both of you are concerned that the process inhibits the development of new chemicals and yet, apparently, about two-thirds of the chemicals for which EPA receives submittals never do get put into production.

What is the connection between those two? Is your answer a complete one that you are being asked to submit by your potential customers, make these submittals before any decision is made about marketing?

Mr. HURST. Senator, when we get involved in the research of a new chemical and we are forced to submit a PMN we may be willing to do so because we at that point have encouragement that there is an opportunity available to us. As we proceed through the R&D program and find out the chemical doesn't live up to that potential, then it is dropped.

Senator GORTON. The two-thirds seems to be a rather high number.

Mr. HURST. It is difficult to analyze that number without having access to all of the numbers that the EPA would have available.

Senator GORTON. Mr. Scott, do you have anything to say?

Mr. SCOTT. If our marketing department had something to do with submitting, I am sure it would be higher than two-thirds failure rate. They tend to be optimistic as to the development.

Mr. HURST. There is a very high failure rate of the new materials at the early stage of the development. That is one of our concerns why the impact of innovation is so high. The exemption program would help correct this.

Senator GORTON. I would like to thank you both for your help and your enlightenment, and with that we finished with our questions. And the meeting is adjourned. Thank you.

[Whereupon, at 4 p.m., the subcommittee recessed, to reconvene subject to the call of the Chair.]

[Statements submitted for the record follow:]

TESTIMONY OF
J. CLARENCE DAVIES
EXECUTIVE VICE PRESIDENT
THE CONSERVATION FOUNDATION
BEFORE THE
SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL
OVERSIGHT, ENVIRONMENT AND PUBLIC WORKS COMMITTEE
U.S. SENATE

AUGUST 4, 1982

My name is J. Clarence Davies. I am Executive Vice President of The Conservation Foundation, an environmental research and communications organization located in Washington, D.C. The Foundation has had an active program of research and policy dialogues on toxic substances issues for the past six years. I personally have been closely involved in the evolution of TSCA since its initial inception in the Council on Environmental Quality in 1970. I appreciate having the opportunity to appear before you today.

I will give a brief overview of the progress, or lack thereof, that has been made in implementing TSCA. I will then address three areas on which the committee has invited comments: negotiated testing agreements, the premanufacture notification process, and international harmonization. The views expressed will be my personal views, not necessarily those of The Conservation Foundation as a whole.

TSCA Implementation

It is an understatement to say that, overall, the implementation of TSCA has been a slow and difficult process. The reasons for this are several: the act is complex; it is, in many respects, a novel and untried approach to dealing with a broad range of major environmental problems; implementation must rely heavily on the science of toxicology which is still in a primitive stage; and actions taken under TSCA's authorities directly affect the interests of a large number of powerful groups. All of these factors have been obstacles to effective implementation.

There are three key sections of TSCA: Section 4, which authorizes EPA to require manufacturers to test chemicals; Section 5, which requires manufacturers to submit a notification to EPA 90 days before manufacturing a new chemical; and Section 6, which authorizes EPA to impose a variety of restrictions on a chemical if it determines that the chemical poses an unreasonable risk to human health or the environment.

The failure to promulgate any testing rules under Section 4, although a large number of chemicals had been recommended for testing by the Interagency Testing Committee, led to a 1979 court order requiring EPA to take faster action to implement Section 4. The Reagan administration has responded to the court order in two ways: first, by finding that a number of the chemicals nominated by the ITC do not require testing, and second by trying to negotiate voluntary testing agreements with the chemical

manufacturers. I shall discuss the voluntary agreements approach in more detail later. To date, no final testing rules have been issued by EPA.

I will also deal with implementation of Section 5, the new chemicals notification provision, later. I would like to note that one important authority under Section 5, the authority to require notification for significant new uses of chemicals, has not been used at all. One significant new use rule was proposed under the Carter administration but never became final. The current leadership of the Office of Toxic Substances has shown interest in this provision, and it is to be hoped that its potential as a major public health safeguard will be realized.

Efforts to use TSCA's Section 6 to actually control unreasonable risks of existing chemicals have been almost nonexistent. The statute itself banned the manufacture and use of polychlorinated biphenyls (PCBs) except for totally enclosed uses or uses that the EPA Administrator found would not pose an unreasonable risk. As interpreted by EPA this ban affected only about 1% of the uses of PCBs. Marking and labeling rules for PCBs may have had some effect in reducing the amount of PCBs entering the environment, but the effect is insignificant compared to the amount of PCBs already in the environment. For the past several years there has been no domestic manufacture of PCBs and probably no importation of them.

OTS has focused its control efforts on two other chemicals in addition to PCBs. Working in conjunction with the Food and Drug Administration, EPA used TSCA's Section 6 to prohibit the

use of chlorofluorocarbons (CFCs) as propellants in nonessential aerosol products. An advanced notice of proposed rulemaking under TSCA outlined approaches for restricting other uses of CFCs, but the attempt to deal with other CFC uses has been abandoned by the Reagan administration.

Much effort was devoted to considering controls on various uses of asbestos, and in December 1979 an advance notice of proposed rulemaking solicited views on such controls. No rules were ever proposed. In 1981 the Office of Toxic Substances submitted to OMB a rule requiring schools to report on asbestos hazards. OMB delayed the rule for almost a year, but has now finally given its approval to EPA to proceed. The oversight functions of your committee would be well served if you examined the role currently being played by OMB in environmental regulatory decision-making..

In summary, there has been very little formal implementation of the key provisions of TSCA. Some other sections of the act, such as Section 8(e), have been more successful. Many chemical industry representatives claim that the act has resulted in major voluntary improvements in the way the industry considers and deals with potential hazards. This may well be so, although there is no good empirical evidence to confirm or deny it.

Negotiated Testing Agreements

In an attempt to surmount the difficulties of promulgating formal testing rules, the Office of Toxic Substances has turned to the possibilities of negotiating voluntary testing agreements

with the manufacturers of chemicals to be tested. These attempts have met with considerable suspicion on the part of environmental and consumer groups.

It is possible that the voluntary approach can be made to work. But from a public health and environmental quality point of view there are four key questions that must be addressed:

- Are there safeguards to assure that the voluntary testing procedures will actually conform to the standards that might reasonably have been imposed had Section 4 rules been written?

- Will test results and the details of the tests be disclosed publicly, as would be the case if the tests had been performed under a TSCA testing rule?

- Will tests be performed in a timely manner?

- What happens if tests are not performed well and promptly?

OTS has not yet structured a voluntary testing system that satisfactorily answers these questions. The initial approach taken by OTS lacks most of the procedural safeguards that would be provided if testing were required by a rule. The voluntary approach may be a fruitful one to pursue, but it may also be that an adequate voluntary system will be even more cumbersome and difficult to implement than following the procedures specified in the statute.

The Premanufacture Notification (PMN) Process

The premanufacture notification provisions of TSCA are among the most important authorities in the act. They represent the

key to preventing damage from toxic substances, as contrasted with remedying problems after damage has already occurred.

In my view the PMN process has not worked well. The major problem has been that the health and safety data submitted with the notifications has simply not been adequate to determine whether the new chemical may pose an unreasonable risk.

Of the 659 PMNs submitted in 1981, none contained test data on chronic health effects. Only 15% contained data on mutagenicity screens, a quick and inexpensive test to indicate whether the chemical might cause chronic effects. Less than half the notices contained data on acute health effects, such as skin or eye irritation, and only 10% contained any data on environmental effects. 43% of the notices contained no toxicity data at all.

To accurately determine the full magnitude of the problem posed by the inadequacy of the data, one would have to match the toxicological data submitted for each chemical with the proposed production volume, uses, and worker exposure of that chemical. We have not been able to do that because of the lack of access to trade secret information. However, last month the Subcommittee on Commerce, Transportation, and Tourism of the House Committee on Energy and Commerce initiated a study by the Office of Technology Assessment to examine in detail the adequacy of the data submitted in PMNs. We have been urging the House Subcommittee to initiate such a study for some time, and I am hopeful that it will provide the most complete and objective

assessment of the PMN data that can be done. The study is scheduled to be completed in about three months.

EPA has recently proposed to exempt a large portion of new chemicals from the PMN requirements. The basic principle of exemptions makes sense, because there are categories of chemicals which can be anticipated with a high degree of accuracy not to pose unreasonable risks. However, the exemption proposal suggested by EPA is both complex and sweeping, and we have a number of serious problems with it. I will very briefly outline my major comments on the exemption proposal:

- The exemption for chemicals manufactured in quantities of less than 1,000 kilograms per year is probably sound.

- The exemption for chemicals manufactured in quantities of less than 10,000 kilograms per year is too high. There is no good way to ascertain exactly what the right volume-of-production cut-off should be. However, 10,000 kilos is ten times the production volume allowed to be exempted under the new chemical regulatory scheme of the European Economic Community. In fact, under the EEC directive, when annual production of a chemical reaches 10,000 kilos, the manufacturer may be required to conduct a second tier of tests, including a fertility study, a sub-chronic toxicity study and a variety of ecotoxicology studies. As the EPA exemption notice admits, "unless potential environmental impacts are assessed and releases properly controlled, low volume chemicals can have the potential to present significant risks in a variety of circumstances." (Chem. Reg. Reporter, p. 297)

- The exclusion of all site-limited intermediates is too broad and has the potential of creating significant unreasonable risks. Many site-limited intermediates are highly toxic and, if not properly handled, can cause severe health risks. The case of BCME at Rohm and Haas is probably the best documented example. Furthermore, the exemption proposal provides a major incentive for companies not to conduct toxicological tests on chemicals subject to exemption by assuming that they are exempt unless test data indicate the contrary. The site-limited intermediate exemption should be limited to specific categories of intermediates designated by EPA. Other intermediates could be exempted if toxicological testing indicated they would not pose an unreasonable risk.

- Both the 10,000 kg and the intermediate exemption would be conditional on review of the chemical by a qualified expert. However, the expert's review would not be sent to EPA which instead is proposing an "audit program" to check on the reviews. This is truly ridiculous. The cost to industry of giving the reviews to EPA should not exceed the cost of a 20¢ stamp, and the information should be required to be submitted to the agency.

- Exemptions for broad categories of polymers are probably justifiable. EPA expects to issue proposed polymer exemptions shortly.

- The exemption policy apparently does not call for any penalty to be applied to a manufacturer who considers a chemical exempt when in fact a PMN should have been submitted. This is

true even if the action of the manufacturer was willful or negligent. This aspect of the proposed policy should be reconsidered.

There is, or at least should be, a close relationship between the exemption policy and the adequacy of data submitted with the PMNs. One of the difficulties EPA had in formulating a rational exemption policy was to avoid requiring more careful review of exempted chemicals than of non-exempted ones. Hopefully, if a reasonable exemption policy is promulgated in final form, EPA will begin to use Section 5(e) and the other powers it has to assure that an assessment of risk can be made on the basis of the PMN information.

International Harmonization

The chemical industry today is truly international. Therefore, disparities between U.S. chemical regulations and those of other industrialized countries have the potential to significantly disrupt international trade in chemicals. This, in turn, could adversely affect not only the U.S. chemical industry but also many other vital U.S. industries that depend on chemical imports.

Significant progress in harmonizing chemical regulations has been made through the Organization for Economic Cooperation and Development (OECD). Currently, however, there is a major dispute between the U.S. and the other OECD nations over the wording of an agreement on MPD, the minimum premarket data set. A number of alternative proposals have been suggested by the parties

involved, and some of the differences have hinged on the placement of a comma or the choice of a preposition. We remain hopeful that a compromise can be reached.

In the longer run, the U.S. has much to learn about chemical regulation from the other industrialized nations and they, in turn, have much to learn from us. The European Sixth Amendment has the potential to be a more effective regulatory framework for new chemicals than TSCA, and the actual operating experience in Europe should be carefully monitored.

This concludes my prepared remarks. I would be happy to answer any questions you may have.

TESTIMONY OF
JACQUELINE M. WARREN
NATURAL RESOURCES DEFENSE COUNCIL

Introduction

The Natural Resources Defense Council (NRDC) is a national non-profit environmental organization supported by 40,000 members who are dedicated to the wise use of the nation's land and water resources, and to the protection of human health and the environment. Since its inception in 1970, NRDC staff attorneys and scientists have been involved in administrative, legal and legislative efforts to control involuntary exposures to toxic and especially cancer-causing substances in the environment, and among other statutes, have monitored the EPA's implementation of the Toxic Substances Control Act (TSCA) since its passage in 1976. We welcome this Subcommittee's oversight of EPA, and appreciate this opportunity to present our views on the Agency's recent performance in implementing the Act.

TSCA was passed in response to repeated disclosures about the severe adverse health, environmental and economic damage inflicted by such widely used substances as asbestos, PCBs, kepone, vinyl chloride, and PBBs, to name but a few.

The Act was intended to remedy the lack of legal authority either to prevent such problems from arising, or to deal adequately with them after the fact of injury or serious risk was established.

The clearly-stated overriding purpose of TSCA is to prevent unreasonable risks of injury to health and the environment from exposure to toxic substances. The basic objectives of the law, as set forth in §2, are that adequate data on the effects of chemicals should be developed by those who produce them; that EPA should have adequate authority to regulate chemical substances which present an unreasonable risk of injury to health and the environment; and that undue or unnecessary burdens on commerce and innovation should be avoided in "fulfilling the primary purpose of the Act to assure that such innovation and commerce in chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." (TSCA §2(c)). (emphasis added).

To achieve these purposes, Congress provided EPA the authority to require that chemicals be tested to determine whether they are hazardous; to restrict or even prohibit their manufacture and use in appropriate circumstances; to screen new chemicals to identify potential "bad actors" before, rather than long after, their entry into commerce; and to gather from the chemical industry and elsewhere the information

necessary to support regulatory decisions. Extensive opportunities for public input and involvement were also included in the statutory framework in recognition of the public's right to know the basis of decisions concerning the effects of toxic substances on health and the environment.

In each of the aforementioned areas of statutory authority and responsibility, a clear pattern has emerged at EPA during the past year. It is a pattern of apparent disregard for the primary purpose of TSCA, which is protection of health and the environment, in favor of eliminating those TSCA requirements, both statutory and administrative, that the chemical industry deems burdensome. To accomplish this end, EPA initiated a series of steps designed to transform TSCA into an essentially voluntary program for the testing, screening and control of toxic substances.

Examples of the voluntary approach are readily apparent. Where the statute calls for rules to govern the testing of chemicals identified by an expert inter-agency committee as the highest priority candidates for testing, EPA instead is negotiating voluntary and unenforceable testing programs which effectively exclude the public and frustrate several other statutory provisions keyed to §4 test rules. Where the statute requires premanufacture screening of all new chemicals by EPA, the Agency instead is proposing broad exemptions. Thus, "qualified experts" employed by chemical producers will certify, but need not substantiate to EPA, the basis

for their conclusions that more than 50% of new chemicals warrant complete exemption from premanufacture screening. Finally, where the statute directs EPA to act to control existing chemical hazards, the Agency has announced that it will do so only as a last resort, preferring voluntary control measures instead.

The poor record of the chemical industry in voluntarily preventing and controlling chemical hazards in the past is well-established. It led to the enactment of TSCA in 1976. Yet, the net result of the Agency's new approach is that the principal authorities given to EPA by Congress to prevent and control chemical hazards are being delegated to the regulated industry for initial decision-making. EPA's abdication of its regulatory responsibilities under TSCA has prompted critics and cartoonists across the country to re-name it the Industrial Protection Agency. We strenuously oppose the transformation of EPA into a paradigm of the captive agency syndrome and urge you to insist that the current leadership of the Agency carry out the laws as written.

This assessment of the EPA leadership's performance is not made lightly. Despite repeated criticisms of EPA by

members of Congress, the EPA Administrator's own Toxic Substances Advisory Committee, and organizations such as NRDC, it is clear the mandate of TSCA is not being fulfilled. Instead, the criteria for identifying and assessing risks are being redefined to justify decisions not to act, and the few strides made in the past to control the introduction of new toxic substances into commerce, and to begin testing widely used chemicals suspected of being toxic, are being reversed. Moreover, the regulated industry has become the principal, if not the exclusive, source of information and initiatives for EPA. NRDC's principal concerns regarding the current administration's implementation of the chemical control provisions of TSCA are described in more detail below.

A. Inadequate "Voluntary" Testing Schemes are Being Substituted for Testing Rules

Section 4 of TSCA requires EPA to propose test rules or decide that testing is not necessary for chemicals designated as high priority for testing by a committee of experts, the Interagency Testing Committee (ITC), within one year of such designation. Chemicals recommended by the ITC are selected because they are produced and used in very large quantities and have exposure potential and biological or chemical properties that are likely to pose risks of cancer, gene mutations, birth defects, or environmental damage. When

EPA failed to act on the first recommended priority chemicals within the statutory period, NRDC brought suit. In February 1980, a United States District Court ruled that EPA was required to act within 12 months after receiving the ITC's recommendations, and in January 1981, placed EPA on an expedited schedule for action on the listed priority chemicals.* According to the schedule, EPA was ordered to propose test rules or decide that testing is unnecessary for 11 priority chemicals in 1981, 13 in 1982, and 13 in 1983.

Although in affidavits to the court, various EPA officials have represented that the deadlines are being met, events over the past year suggest the contrary. More than two years have passed since the proposal of the first testing rules for three chemicals on the list and more than one year since a second proposal for three more chemicals, but no final rules have been issued. Agency personnel have told NRDC that there are no present plans to issue those rules in final form. Instead, negotiations are underway between EPA and various industry associations regarding the development of voluntary testing schemes in lieu of testing rules under §4 for the priority chemicals. Indeed, primary reliance on such schemes was formally announced in March as EPA policy for testing of the priority chemicals.**

* NRDC v. Costle, 14 ERC 1858, ___ F.Supp. ___ (S.D.N.Y. 1980).

** 47 Fed. Reg. 13012 (March 26, 1982).

NRDC recognizes that voluntary testing by the manufacturers of chemicals is an objective of TSCA, and we would welcome the widespread acceptance of this responsibility by the chemical industry. Voluntary testing schemes for the priority chemicals on the court-ordered schedule, however, raise issues that voluntary testing of other chemicals does not. The priority chemicals are those suspected by an expert committee of posing potential hazards to health and the environment, and for which specific tests have been recommended. They are covered by one of the few action-forcing provisions of TSCA, §4(e), and decisions to issue test rules for them trigger numerous other statutory requirements. For example, development of test rules involves extensive public input (notice-and-comment rulemaking), Federal Register notice and public access to data produced pursuant to a testing rule [§§4(e) and 14(b)], submission of test data with a PMN [§5(b)]; enforceable laboratory procedures and testing deadlines (§15); and notification to foreign governments of the export of a substance subject to a test rule (§12).

Acceptance by EPA of voluntary testing schemes developed by industry as a substitute for rulemaking will result in industry testing commitments that are not enforceable, may not be adequately comprehensive, may never be completed, and which are developed with little, if any, public oversight and involvement. EPA could correct some of these deficiencies by

supplementing the voluntary programs with rules specifying necessary additional testing and use of validated protocols, by imposing enforceable deadlines for completion of the tests, and by involving the public to the same extent as §4 provides. While EPA has offered to meet with members of the public at various points during the development of voluntary testing proposals, the public will not be involved in the actual negotiation process. It also appears that EPA is not going to impose additional requirements to cover the deficiencies in the proposed programs that have been described above.

In summary, NRDC views the open-ended and admittedly insufficient voluntary testing approach as a poor substitute for the test rules TSCA intended the Agency to promulgate for the priority chemicals. While incentives for industry to initiate voluntary testing should be encouraged, we do not believe that the priority chemicals will ever be adequately tested unless EPA begins to issue testing rules in final form and attaches to the voluntary proposals the guaranties of expedition, completion, adequacy of comprehensiveness, public involvement, and connection with other TSCA provisions that Congress intended in §4(e).

B. Broad Exemptions from Premanufacture Notification Requirements Have Been Proposed

A second example of the "voluntarization" of TSCA and exclusion of the public from decision-making regarding new chemicals is provided by the recently-proposed rule carving out broad exemptions from the premanufacture notification provisions of §5 for new chemicals.

The purpose of premanufacture notice (PMN) to EPA is clearly stated in the Conference Report on TSCA:

The provisions of the section reflect the conferees' recognition that the most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized. [H.Rep.No. 94-1679, 94th Cong., 2d Sess.65(1976).]

The existing PMN system is not accomplishing the Congressional objective. EPA has received more than 1,400 PMN notices since April 1979. As of May 31, 1982, Agency figures showed that approximately 50 percent of the notices were submitted with no data whatever on the toxicity of the new chemical. In calendar year 1981, more than 41 percent of the notices submitted by large companies with sales greater than \$500 million a year contained no toxicity data. These statistics suggest that the PMN program as currently implemented is not encouraging the voluntary development of premanufacture

health and environmental effects data, not even the most basic acute toxicity data. On the contrary, it appears that many of the largest chemical producers, who can best afford to test their products prior to marketing, are not doing so.

The absence of toxicity data means that health and environmental effects assessments of new chemicals must be based upon data on other chemicals which are structurally similar, to the extent that EPA staff can identify such data. The end result is that EPA, rather than the chemical industry, has been bearing the burden of locating data relevant to the potential hazards of new chemicals -- and a very large percentage of new chemicals are entering the marketplace without an adequate assessment of the hazards they, as opposed to their structural analogs, may pose to health and the environment.

Although EPA, on January 27, 1981, published as a policy statement a recommended approach to premanufacture testing, such testing is not required under TSCA. The policy statement endorses and recommends that chemical producers develop the Minimum Premarket Data set now provisionally agreed upon by most of the 24 countries of the Organization for Economic Cooperation and Development as an appropriate starting point for the prediction of risk of new chemicals. The OECD Premarket Data Set is almost identical to the premarket testing scheme adopted last year and currently being implemented by the

member countries of the European Common Market. Such a testing scheme is not a requirement in the United States, however. Moreover, the American chemical industry is adamantly opposing either endorsement by the United States of the OECD Minimum Premarket Data set or amendments to TSCA which would impose on United States companies the same testing requirements their foreign competitors are now being required to meet. Ironically, American chemical producers are now required to do more testing of their new chemicals for sale in the Common Market than they routinely do for the domestic market.

As the figures graphically demonstrate, in a large number of cases, chemical producers in this country are not voluntarily testing their new chemicals to identify adverse health or environmental effects. Instead, six years after TSCA was enacted, the chemical industry in the United States generally appears to be conducting business as usual, and continuing to use the workplace, the general public and the environment as a testing laboratory for determining the adverse effects of their products. It is also clear that the industry's frequent claim that testing requirements are not needed because new chemicals are being adequately tested is simply not true.

Instead of focusing on ways to stimulate the chemical industry to develop more toxicity data on new chemicals, EPA has recently proposed sweeping exemptions from the PMN requirements of §5 of TSCA. Responding to a petition by the Chemical Manufacturers Association, EPA has developed a proposal that

could exempt 50% of new chemicals from full PMN review. The exemptions will be for new chemicals produced in volumes under 22,000 pounds a year, for new chemicals produced and consumed at the site of manufacture, regardless of volume, and for new polymers. Although a small number of new chemicals exhibiting certain very toxic effects will not be eligible for exemption, new chemicals will generally be exempted if a "qualified expert" employed by the producer certifies to EPA that the chemical is eligible. EPA will not know the basis for the "expert's" conclusion, however, unless the Agency specifically requests substantiation.

Congress provided in §5(h)(4) for exemptions from all or part of the PMN requirements "upon application and by rule," contingent upon a finding by the Administrator that there will be no resulting unreasonable risk. We wonder how EPA can make such a finding for so many new chemicals, sight unseen and in virtually complete reliance upon the unsupported assertion by a representative of the manufacturer that the chemical is eligible for exemption from the PMN requirements.

The Agency is proposing to require that a brief notice identifying the chemical, the site of manufacture, and the anticipated use be submitted 14 days prior to manufacture, but with no substantiation of the "qualified expert's" conclusion that the new chemical is eligible for exemption. This approach will impose upon EPA the burden of attempting to evaluate the claim of eligibility in a very short period of time with no indication whatever of how and why the "expert" reached the conclusion. In our view, this proposal

would improperly delegate to the chemical industry the authority to screen new chemicals before they are commercially manufactured.

Congress intended EPA, which is supposed to be concerned with protecting more than merely the interests of the chemical industry, to screen new chemicals in the first instance. In the past, the chemical industry introduced a number of new chemicals into commerce that resulted in widespread injury to health and the environment. The PMN process was designed to prevent this from occurring in the future, but with "qualified experts" from the chemical industry instead of EPA as the first line of defense, there can be little assurance that the public will in fact be protected.

C. Voluntary Risk Controls That Could Destroy the Statutory Design of TSCA Are Being Sought in Preference to Exercise of the Basic Regulatory Authorities of Section 6

Section 6 provides EPA with broad powers to control exposures to toxic substances, including imposition of warnings and notices, geographic or poundage limitations, restrictions on use, or outright prohibitions. The authority reaches every aspect of chemical production, from manufacture to processing, distribution in commerce, use and disposal.

In the previous administration, EPA has exercised its §6 authority only three times: to prohibit the use of non-aerosol chlorofluorocarbons, to prevent the burial of

dioxin-contaminated waste at a manufacturing site in Arkansas, and to implement Congressionally-mandated requirements for marking and disposal of PCBs as well as the phase-out of manufacture and open system uses of PCBs. The current administration's principal activities under §6 are not much more impressive. EPA has recently issued watered-down requirements for the inspection of deteriorating asbestos structural components in public schools, a Carter administration initiative that was promulgated only after heavy Congressional pressure was brought to bear on the Agency. In addition, pursuant to a court-ordered schedule, EPA is re-writing the PCB ban regulations overturned in 1980 by the D.C. Circuit. No other §6 actions are either pending or contemplated.

Instead of establishing a program to identify and control existing chemical hazards, EPA is in the process of developing a "voluntary risk management advisory" approach whereby companies faced with potential §6 control actions would agree to develop voluntary controls on the chemical involved. Although press reports are currently the only source of information about the proposal, it is clear that the entire statutory scheme of TSCA would be defeated by the adoption of voluntary approaches to implementation of what is inherently a regulatory statute.

As in the case of voluntary testing instead of rules under §4, voluntary controls under §6 will effectively write

out of TSCA the public involvement in decision-making guaranteed by the rulemaking provisions of §6(c), the effective date requirements of §6(d), the authority to gather information from small manufacturers under §8(a)(3), requirements for export notification under §12, the authority to impose import restrictions under §13, the mandatory compliance requirements of §15, the authority to impose civil and criminal penalties for non-compliance under §16, the specific enforcement and seizure requirements of §17, judicial review under §19, citizen enforcement under §20, citizens' petitions under §21, and employment effects studies and hearing rights under §24. In sum, adoption of a voluntary approach in lieu of rules under §§4 and 6 will destroy the statutory framework by rendering inoperative all of the statutory sections that depend upon the issuance of rules by EPA to implement the law. We would prefer that Congress repeal TSCA directly than permit the systematic evisceration of its key authorities as EPA now proposes.

D. EPA's Science Is Being Subordinated to Politics and Ideology

Concerns about EPA's will to act have been heightened by the recent determination that the risks posed by continuing exposure of the population to formaldehyde are "insignificant" and do not warrant any investigation of possible regulatory options at the present time. Formaldehyde has been shown to be carcinogenic in laboratory animals and is very widely used

in the United States. In NRDC's view, EPA's decision not to consider formaldehyde further as a candidate for regulatory action violates §4(f) of TSCA, which provides that:

Upon receipt of (1) any test data required to be submitted under this Act, or (2) any other information available to the Administrator, which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations or birth defects, the Administrator shall, within the 180-day period beginning on the date of the receipt of such data or information, initiate appropriate action under §§5, 6 or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable....

In the spring of 1981, the staff of the Office of Pesticides and Toxic Substances recommended that formaldehyde and di(2-ethylhexyl) phthalate (DEHP), another carcinogenic and widely-used chemical, be designated for priority evaluation under §4(f). Subsequent to receiving these recommendations, the Deputy Administrator of EPA held a series of secret "science courts", principally involving industry representatives, on both chemicals. The propriety of conducting such "science courts" was the subject of a number of Congressional hearings late last year. Thereafter, the recommendations of the EPA staff regarding both chemicals were specifically reversed, and EPA in February issued a document announcing its decisions not to consider formaldehyde or DEHP as candidates for possible regulation.

Perhaps the most troublesome aspect of the Agency's decision on formaldehyde is the reversal of ten years of EPA and federal regulatory policy on assessing the risks of carcinogenic substances. At the same time that the CPSC decided to ban the use of urea formaldehyde foam insulation on grounds of carcinogenicity and acute toxicity, EPA dismissed the risk of exposure to formaldehyde, including to urea foam insulation, as "insignificant."

It is now clear that the Office of Toxic Substances is making regulatory decisions about carcinogenic chemicals that run directly contrary to the prevailing views of the scientific community. EPA's views are, however, quite consistent with positions advanced by the Formaldehyde Institute and other industry representatives in their efforts to forestall or prevent regulation of carcinogenic chemicals.

Although regulated industries have consistently argued in favor of conclusive proof of harm to humans as a prerequisite to regulation of cancer-causing substances, until now none of the federal regulatory or scientific bodies has ever espoused this approach because it is insufficiently protective of public health. Moreover, actions to prevent harm rather than merely to react after the fact have been uniformly upheld by the courts:

Courts have traditionally recognized a special judicial interest in protecting the public health "where the matter involved is as sensitive and fright-laden as cancer." Where the harm

envisaged is cancer, courts have recognized the need for action based upon lower standards of proof than otherwise applicable.

Certified Color Manufacturers Association v. Mathews, 543 F. 2d 284 (D.C. Cir. 1976), quoting EDF v. EPA [DDT], 465 F.2d 528, 538 (D.C. Cir. 1972).

The rationale for this approach is simple. As one court stated in upholding EPA's 1977 prohibition on the further discharge of PCBs into water under the Clean Water Act:

What scientists know about the causes of cancer is how limited is their knowledge. [I]t may take decades for human exposure to carcinogens to result in cancer; in the meantime, the case for inferring a cancer danger with respect to an incompletely understood substance is vigorously debated. If regulation were withheld until the danger was demonstrated conclusively, untold injury to public health could result.

EDF v. EPA, 598 F.2d 62 (D.C. Cir. 1978).

The policy reversal reflected in the tentative decisions not to regulate formaldehyde and DEHP represents the espousal by the TSCA Program of industry arguments regarding the regulation of carcinogens which have been repeatedly rejected in the past for the reasons stated above. Thus, the prospects grow increasingly dim for meaningful Agency action during this administration to reduce exposures to existing cancer-causing and other toxic substances.

Conclusion

TSCA was enacted in 1976 in response to strong public demand for basic changes in the way chemicals are developed and introduced so that the potential kepones and PCBs of the future could be identified in the laboratory rather than in medical records or in monetary losses caused by contamination incidents. Congress' intention that EPA use TSCA to begin to remedy such problems has not yet been carried out, and the problems caused by toxic substances are still very much with us.

Despite their assertions to the contrary, this Administration does not have a mandate from the American people to weaken the nation's environmental and health protection statutes. A series of recent public opinion polls confirm that there is overwhelming support for continued and strengthened efforts to protect health and the environment, especially in the area of toxic substances control. Unfortunately, the Agency's apparent willingness to re-define many hazards as "insignificant" risks, their espousal of a voluntary controls approach, and ongoing budget cuts which reduce the Agency's resources all bode ill for effective measures to protect health and the environment in the foreseeable future.

Statement of the
CHEMICAL MANUFACTURERS ASSOCIATION

The Chemical Manufacturers Association (CMA) welcomes this Subcommittee's oversight of the Toxic Substances Control Act (TSCA) and appreciates this opportunity to provide the Subcommittee its views on the Environmental Protection Agency's (EPA) implementation of TSCA.

CMA is a nonprofit trade association whose company members represent more than 90 percent of the productive capacity of basic industrial chemicals within this country. From early Congressional consideration of a toxic substances law, to the passage of TSCA in 1976, and through the succeeding years of its implementation, CMA and its member companies have maintained an active interest in this law. CMA has been a constructive participant in EPA's efforts to implement TSCA. Since TSCA significantly affects almost all phases of a chemical company's operations, CMA and its individual members have been interested in how EPA plans to implement substantive provisions of the Act. CMA supports the objective of TSCA -- preventing and controlling unreasonable risks to health and the environment. We continue to support a timely and reasonable implementation of the Act that is in accordance with this objective.

INTRODUCTION

The Toxic Substances Control Act was signed into law on October 11, 1976, and became effective on January 1, 1977. A complex and detailed statute, TSCA empowers EPA to evaluate and,

if necessary, regulate the effects of chemical substances and mixtures on human health and the environment. TSCA's coverage is comprehensive. It potentially applies to all chemicals manufactured, processed, distributed, used or disposed of in the United States, except where these chemicals are already regulated under certain other federal laws. TSCA thus affects not only the chemical industry itself, but also impacts other industries and parts of society dependent upon its products. The present law reflects Congress' decision to adopt a legislative approach that offers protection to human health and the environment while preserving an innovative and dynamic chemical industry.

These interrelated concerns are reflected in Section 2(b) of TSCA, which states the congressional policy. This provision declares that the Act's objectives are: (1) to encourage manufacturers and processors of chemical substances and mixtures to develop adequate data concerning the effects of chemicals on health and the environment; and (2) to authorize EPA to take regulatory action against those substances and mixtures which present an unreasonable risk of injury. Nevertheless, the Congressional policy emphasizes that these goals are to be achieved without unduly impeding, or creating unnecessary economic barriers to, technological innovation. Moreover, Section 2(c) states that it is the intent of Congress that EPA act in a reasonable and prudent manner, reflecting a careful consideration of the economic and social impact of any requirements that the Agency adopts under the Act.

CMA and its individual member companies have actively worked with EPA since the passage of TSCA. We have submitted extensive comments and constructive suggestions on the technical and legal merits of each proposed rule. Under the former administration we always felt free to discuss with EPA their understanding of the statute, their goals, and their regulatory proposals. This has not changed under the present administration. What has changed, as we see it, is the basic approach of implementing the law.

EPA has found that it can get faster and more effective results through a focused approach with specific reasoned objectives based on good science. This requires commitment on the part of both EPA and industry, considerable discussion and an appropriate measure of trust while maintaining the necessary arms-length posture. In its efforts to negotiate, EPA has emphasized to industry and to the public the need for the Agency to base their positions on facts. This infusion of science and fact-finding into the decision-making process comes as a breath of fresh air to an industry which is based on technological know-how. We believe the public is far better served when actions are based on the best available information than when facts are selected, chosen or ignored in order to fit preconceived ideas for regulation produced by fears and emotions.

By applying the approaches that we have just outlined, EPA has been able to take major steps to implement substantive sections of TSCA. While EPA should be commended for reaching these

milestones, CMA wishes to point out that we do not always agree with EPA on all provisions of its final and proposed rules. In some instances, we believe EPA has disregarded CMA's concerns or has provided inadequate justification for the course it chose to take. A more detailed review of EPA's implementation of TSCA provisions follows.

SECTION 5: PREMANUFACTURE NOTIFICATION (PMN)

Section 5 of TSCA requires EPA to review new chemicals, and significant new uses of existing chemicals, in advance of commercial introduction. This enables EPA to identify their potential effects on human health or the environment before chemicals enter commercial production. This section also outlines the authority for EPA to delay or prevent the manufacture and use of such chemicals until companies develop more information on their health or environmental effects. In addition, the Agency can permanently restrict manufacture or use where available evidence indicates that a chemical presents a significant risk.

When Congress passed TSCA, it recognized that Section 5 would have a far-reaching impact on the future development of new chemicals and new applications for existing chemicals. Section 2 of TSCA imposes a special obligation on EPA to minimize adverse economic effects, particularly relating to technological innovation, in implementing Section 5. In seeking to balance the burdens on manufacturers with the preventative purpose of the Act,

Congress designed Section 5 to operate as a notification and review function, having rejected an intensive premarket clearance for all new chemicals. Congress, after six years of debate, chose to make TSCA a balancing-type law which weighs many factors in making an unreasonable risk determination.

Premanufacture notification is confined by the statute to information that is known to or reasonably ascertainable by the manufacturer. In enacting Section 5, Congress specifically rejected a system of mandatory premanufacture testing for new chemical substances. Instead, it tailored testing for particular chemicals based on a careful examination of available data concerning their properties, uses and potential risks. As such, TSCA gives EPA authority to obtain test data under appropriate circumstances specified by Section 5(e) of the statute.

Under the prior EPA administration, the Agency published proposed rules for implementing PMN provisions. In the first proposal, we believe EPA exceeded its statutory authority when it published a burdensome PMN form which called for nearly 40 pages of mandatory information and 20 more pages of optional information. The second proposal required somewhat less information, but still more than is contemplated by the statute.

CMA understands that EPA has reviewed all the comments and expects to publish a final PMN rule which will conform to the clear statutory language and legislative history of Section 5.

CMA hopes that if forms accompany the final rule, they will be simpler and more straight-forward than those previously published.

THE PMN PROCESS IS WORKING WELL

While EPA has not promulgated a final PMN rule (and the statute does not require it), experience to date indicates that the PMN process is working well.

In the three-year history of premanufacture notification, companies have submitted over 1,500 PMNs to EPA. These three years have provided EPA an opportunity to establish a staff to evaluate the effects of new chemicals on health and the environment; to establish criteria for determining whether those chemicals present an unreasonable risk of injury; and to establish mechanisms for taking action on new chemicals that raise significant health or environmental concerns. Significantly, EPA has gained insight into the nature of product innovation within industry and the new chemicals it produces.

In the absence of a final rule, manufacturers of new chemicals have complied with the PMN information requirements. EPA officials from both the prior and current administration have maintained that this information has been sufficient for EPA to make regulatory decisions. In those few cases where the Agency did not have sufficient data (about 50 cases), EPA contacted the

submitter for additional data and the submitter agreed to obtain and provide EPA with the necessary data.

Despite claims questioning adequacy of PMN data, approximately 97% of the PMNs submitted contain adequate information. The record speaks for itself -- the PMN program has been highly effective by any reasonable standard.

In addition to requesting manufacturers to supply additional PMN data, EPA has the option under Section 5(e) to issue an order prohibiting or limiting the manufacture, processing, distribution, use, or disposal of the substance. EPA can do this when it determines that: (1) existing information is insufficient to permit a reasoned evaluation of the substance's health and environmental effects; and (2) there may be substantial human or environmental exposure to the substance, or the substance may present an unreasonable risk of injury to health or the environment. To date, the Agency has issued three Section 5(e) orders covering nine chemicals. EPA has indicated in an additional two cases its intention to issue a Section 5(e) order, which resulted in the manufacturers withdrawing their PMNs. This again illustrates that in a high percentage of cases the information needed for review has been available to the Agency.

Also of importance is the report from EPA that many of the new chemicals are of low risk, and that the preliminary assessment is completed in a short period of time. This was reported in

about 50% of the cases which illustrates that a high percentage of the new chemicals being developed do not pose significant safety concerns.

Through its careful review of information submitted with PMNs, its effort to obtain additional information from companies voluntarily and its judicious use of Section 5(e), EPA has carried out its statutory mandate to provide an effective review of the hazards of new chemicals and has followed Congress' intent in implementing Section 5.

PMN EXEMPTIONS

After EPA had gained three years' experience reviewing PMNs, CMA initiated a study (conducted by an independent consulting firm) to examine the types of chemicals being submitted, the nature of the risks they posed, and the cost to manufacturers for complying with PMN requirements. In over two-thirds of a random sample of the PMNs CMA reviewed, the chemicals presented low risks to human health or the environment. In addition, we discovered that the average direct cost for manufacturers to submit a PMN was \$7,500. Costs associated with intermediates and commercial failures bring the total cost burden to approximately \$12,000. Other indirect costs should be added. An earlier EPA-commissioned study by Arthur D. Little, Inc., examined the impact of PMN filing costs on the rate of new chemical introductions into the market. It found that introduction declined proportionately with the costs for filing.

CMA considered this information, along with TSCA's mandate not to impede innovation unduly, and in May 1981, petitioned EPA to exempt certain low-risk chemicals from PMN requirements. Section 5(h)(4) of TSCA gives EPA authority to exempt from PMN requirements chemicals that pose no unreasonable risks to health or the environment. In its proposal, CMA identified categories of chemicals that it believes meet the statutory mandate of no unreasonable risks. These categories include certain polymers, low-volume chemicals and chemicals produced and consumed on a single plant site (site-limited intermediates).

Under CMA's proposal, EPA, the public and industry have safeguards. For example, a low-volume chemical, or a site-limited intermediate (not used in an enclosed process) would be eligible only if it does not have adverse chronic health effects to humans under its anticipated conditions of use. A chemical would be considered capable of chronic health effects if it causes carcinogenic, teratogenic or reproductive effects, or some other persistent illness or injury. Industry will use a qualified expert to evaluate the proposed exempt chemical to ensure it meets the criteria established for qualifying for the exemption. Furthermore, because exempted chemicals would not generally be added to the TSCA Inventory, the Agency would have increased ability to monitor and control those chemicals during the exemption period. Finally, EPA can revoke the exemption upon determining that, notwithstanding the manufacturer's full compliance with exemption terms, the chemical does not meet the criteria on which the exemption is based.

While establishing safeguards to limit availability of the exemption to chemicals of known low-risk status, CMA's exemption proposal for low-risk chemicals supports innovation within the chemical industry by reducing PMN-related costs. Such costs have a direct bearing on marketability of new chemicals. Many new chemicals represent minor improvements over existing materials. The developer must believe that the product is less expensive or more efficient than the existing product. Only then will the new product be brought forth into the marketplace.

Even small increases in price could eliminate the advantage that a new product might enjoy over its already established rivals. The uncertain performance of a new product and lack of customer familiarity with the chemical may deter customers from buying the new material unless sufficient benefit is perceived. Since the price for the chemical is limited by its cost performance in the marketplace, it may not be possible to pass along any unnecessary increases in costs resulting from the PMN.

The dampening effect on competition of PMN costs is often most dramatic where a chemical is produced in small quantities. Since PMN costs are fixed, when small product volumes of new chemicals are involved, the incremental price per pound for PMN filing costs has its greatest impact. As the intended production

volume of a new chemical decreases, the cost per pound of a chemical due to fixed costs (such as PMN) increase significantly. Because most new chemicals start with low expected production volumes, these costs are of particular importance in the go - no go decision to commercialize.

Since production costs and competitiveness are inversely related, PMN-related costs significantly impact low-volume chemicals. Based on comparisons between pre-TSCA and current figures on substances produced in small quantities, the number of new chemicals produced in small quantities is decreasing. Survey data have demonstrated that there are fewer than one-third as many new chemicals being produced today, with expected production volumes under 1,000 pounds, than there were before the PMN requirements went into effect.

We are pleased that last week the Agency proposed premanufacture notification exemptions for site-limited intermediates, low-volume chemicals and polymers. While we will need time to review the proposals, it appears that the Agency's action is a flexible use of its authority which will afford major benefits to the public, EPA and industry. Under these proposals, EPA should be able to focus its efforts on those new chemicals whose health or environmental effects require scrutiny and devote correspondingly less attention to classes of new chemicals that have little or no potential for harm. We believe these rules will go far to protect innovation in the chemical industry by reducing regulatory

burdens on those new chemicals that pose low risks, without compromising EPA's commitment to health and environmental concerns.

TEST MARKETING

Under Section 5(h)(1), EPA may exempt a new chemical substance from PMN requirements in order to permit the substance to be manufactured for test marketing purposes. The applicant must satisfy the Administrator that its proposed test marketing activities will not present any unreasonable risk of injury to health or the environment.

CMA is pleased to note that the review process for test marketing exemptions (TME) at EPA has been streamlined significantly. In fact, the Agency's review of TMEs takes place well within the 45-day period before the scheduled start of production. As a result, companies are now able to use TMEs as a tool in their product development programs. CMA applauds EPA for its success in implementing Section 5(h)(1), and attributes its accomplishment to an overall improvement in the quality and efficiency in the Agency's new chemical review program.

SECTION 4: NEGOTIATED TESTING

Section 4 of TSCA authorizes EPA to promulgate rules requiring the testing of selected chemicals. Also, EPA is required to initiate proceedings within one year from the time the Interagency

Testing Committee (ITC) designates a chemical for testing, leading to a proposed rule or a decision not to require testing. CMA believes EPA's progress in implementing Section 4, through acceptance of negotiated testing programs as an alternative to formal test rules, has several advantages.

For instance, the formal test rule process is time consuming. Progress from the proposed rule stage to a final rule may take years, due to the time it takes EPA to draft various proposals, to respond to numerous public comments, and to promulgate a final rule. By contrast, a negotiated program may be agreed upon in a year or less, and testing initiated shortly thereafter. Using the negotiated approach, EPA will more promptly receive test data on which to base regulatory decisions. Similarly, through negotiations, EPA can obtain information allowing it to expeditiously make decisions not to require testing when such decisions are appropriately substantiated.

The negotiated approach gives all those interested in a particular chemical an opportunity to express their views on testing needs through early contact in informal discussion sessions with the Agency. These sessions are used to reach agreement on all key elements of a test program so that once a test program is written, extensive revisions and delays are unlikely.

Negotiated testing programs, arrived at through multiparty discussions, also encourage the use of good scientific judgment.

Agency and nongovernment scientific experts have an opportunity to work together to identify the critical components of a Section 4 test program in terms of the Agency's regulatory needs. This consultative approach helps ensure that testing will be conducted using the most current state-of-the-art methods. CMA believes that there are sufficient safeguards in the negotiated testing process to ensure that testing is adequate and timely.

Negotiated programs can be designed and implemented without sacrificing TSCA's procedural safeguards. A program typically includes target dates for initiating and completing testing, and a description of the tests to be performed. It is highly unlikely that companies would intentionally violate these written agreements which would jeopardize their credibility and future relationship with the Agency. Furthermore, if at any time EPA is not satisfied with the negotiated test program, the Agency can invoke a Section 4 rule. Interested members of the public can also petition for action under Section 21. Therefore, strong incentives exist for industry not to deviate from the agreed upon program.

In addition, adequate opportunity for public participation exists in the development of a negotiated testing program during the initial scoping meetings and other sessions early in the negotiating process. Once the test program has been defined, the program is published in proposed form for review and comment by interested members of the public. The Agency will then respond to

comments and decide whether to adopt the program in final form. In addition, public files containing meeting materials are kept, enabling anyone to keep abreast of new developments. These practices are fully consistent with the requirements of the law.

Negotiated programs include provisions for disclosing final test results to EPA and for informing the Agency when any significant changes in the testing program are necessary due to unforeseeable problems. Therefore, EPA is kept abreast of the testing progress.

CMA recognizes that negotiated test programs will not completely replace Section 4 rulemaking. Test rules are necessary in situations where no agreement is reached in negotiating sessions regarding what testing is needed. Also, an industry group may want a rule so that EPA can assist in determining the equitable sharing of test costs between those conducting the testing, and those who are not.

Through a series of reports to EPA, the ITC designates chemicals which should be considered for test rules under Section 4(a). Due to statutory time constraints, EPA must always be prepared to implement rulemaking if testing negotiations are not fruitful. This constitutes another procedural safeguard to ensure that these negotiations do not unnecessarily delay the onset of testing.

To date, EPA has accepted four negotiated testing programs. Through negotiations the Agency has also made decisions not to require testing for six chemicals. For several other ITC designated chemicals, industry groups are discussing testing needs and several more such groups are likely to begin shortly. We believe this demonstrates that negotiated testing concept is a viable tool for EPA in carrying out its responsibilities under Section 4. Where used, it has proven to be a more expedient approach to testing decisions under TSCA.

SECTION 8: REPORTING RULES

Section 8 of TSCA is the basic information-gathering mechanism within the Act. It is designed to provide EPA with necessary data for supporting regulatory activities on existing chemicals.

The approach taken by the Agency in its previously proposed recordkeeping and reporting rules was very broad. It appeared that information was being collected for its own sake rather than for a clearly defined purpose. This abundance of information would be beyond the Agency's capacity to process and evaluate in a reasonable period of time. No attempt was made to assign priority in the information-gathering process. Furthermore, the economic impact on industry of these earlier proposals would have been substantial -- a burden consistently underestimated in EPA's analyses.

CMA recognizes that sound and adequate information is necessary for the effective implementation of TSCA. We are encouraged by the more focused approach the Agency appears to be taking now in its recordkeeping and reporting rules. While some differences with the Agency remain, we believe that the type and amount of information being collected will prove more manageable and useful to EPA in meeting its regulatory objectives -- and industry and EPA resources will be used more wisely. The individual rules are discussed below.

Section 8(a)

The final Section 8(a) rule (published June 22, 1982) primarily requires manufacturers of the 250 chemicals listed in the rule to report production, use, and exposure information. The number of chemicals required to be reported by companies was reduced from an original 2,300 to the present 250. This illustrates EPA's sensitivity to the substantial burden which would have been placed on industry in providing such an overwhelming amount of information and on EPA in assimilating so much data. The 250 chemicals included in EPA's final 8(a) rule were selected because they were singled out by the ITC or by Section 8(e) substantial risk notices as chemicals of potential concern. We support the Agency's use of other TSCA activities to help prioritize information collections under Section 8. This more focused approach will conserve resources without compromising the Agency's legitimate information-gathering objectives.

Other aspects of the final Section 8(a) rule are vastly improved and more practical. For example, the rule requires exposure estimates to include only those workers potentially exposed to risk rather than the entire workforce of a chemical plant. The rule also requires customer and processor reporting only if manufacturer reporting fails to account for most of the chemical's potential exposure. In addition, EPA will aggregate and disseminate reported data only if there is no jeopardy of confidential business information being disclosed.

There are, however, provisions of the final Section 8(a) rule that CMA finds troublesome. For example, some companies believe that for some of the 250 chemicals included in the Section 8(a) rule, production, use, and exposure information has already been submitted voluntarily either to ITC or to EPA. Duplicative reporting such as this should be avoided.

Section 8(c)

Section 8(c) requires manufacturers, processors, and distributors of chemicals to keep records of allegations of significant adverse reactions to health and the environment. EPA is in the process of revising its Section 8(c) proposal into a final rule, which will likely be published in early 1983.

In comments on the previous proposal, CMA maintained that EPA's broad definition of "significant adverse reactions"

would result in tens of thousands of allegations and a level of industry recordkeeping and reporting activity far greater than EPA's projections. EPA's proposal also included provisions for automatic reporting if three or more similar allegations are received in one year. CMA maintained that automatic reporting was not authorized by the statute and questioned EPA's use of unsubstantiated allegations in regulatory decision-making. We hope the final rule will reflect these concerns.

While CMA recognizes the value of a final 8(c) rule, we want to re-emphasize that allegations are by definition unsubstantiated, and they could often be inaccurate or misleading. Their role is limited to an indicator of potential concern that requires further investigation. Therefore, they do not deserve the same consideration in regulatory decision-making that is afforded scientifically derived data.

Section 8(d)

Section 8(d) of TSCA requires the submission of lists and copies of health and safety studies. Publication of a final Section 8(d) rule is expected in the near future. The Agency appears to be taking a practical approach which CMA believes will improve the rule's effectiveness while conserving valuable government and industry resources.

CMA is concerned, however, that a provision of EPA's final rule would require automatic trigger reporting on all future ITC chemicals. Based on ITC recommendations, EPA may only be interested in specific effects of concern. If EPA used an abbreviated notice and comment procedure, the Agency could tailor the health and safety studies reporting requirements. CMA feels strongly that a comment period is needed so that unnecessary reporting can be avoided. An abbreviated procedure should not prevent the Agency from meeting its court-ordered and statutory deadlines for responding to the ITC.

INTERNATIONAL TOXIC SUBSTANCES REGULATION

While EPA is well on its way toward implementing TSCA, most of the remaining developed countries are playing catch-up with the United States when it comes to regulating toxic substances. And such laws in the less developed countries either do not exist or are dwarfed by TSCA's scope. Only about a dozen other countries have enacted broad spectrum laws like TSCA. Because of the particular national problems and concerns being addressed, these laws vary in areas of notification and testing required and in the protection of trade secrets.

Over the course of six years, the U.S. Congress carefully crafted a workable, sound law in TSCA. We see no reason at this time to import parts of foreign toxic substances laws, many of which, such as the EEC's Sixth Amendment, are untried.

It should be noted that, as an industry which exported approximately \$21 billion in 1981, the chemical industry is concerned about tariff and nontariff trade barriers. In this regard, CMA generally supports and actively participates in organizations, such as the Organization for Economic Cooperation and Development, which strive to eliminate such barriers. However, given the lack of experience with the various national laws regulating toxic substances, we are opposed to attempts by such international organizations to impose one mandatory international regulatory system. In the testing area, such an attempt is evidenced by the OECD's minimum premarketing set of data (MPD). The MPD not only conflicts with TSCA in that it mandates a fixed battery of tests to be applied for all new chemicals, but it is also questionable for scientific reasons.

CMA believes that the experience obtained during the recent intergovernmental negotiations on MPD indicates that the establishment of one uniform regulatory system for toxic chemicals internationally is clearly premature and probably unwise. We believe that the efforts of international organizations, such as the OECD, should instead be directed to harmonization activities which lead to developing an understanding of regulatory systems, the mutual acceptance of data, and the development of compatible systems. This process, we think, should be a gradual and voluntary one.

CONCLUSION

While EPA has gone far in implementing many of the substantive sections of TSCA, the Agency is busy in implementing remaining sections. We remain committed to provide EPA our technical expertise and practical know-how in resolving problems. CMA believes its contributions benefit not only its members, but our society by reducing the time needed to implement TSCA and by reducing the cost of government.

We will tell the Agency when and why we differ with its approach. More importantly, we will provide practical alternatives, where possible, that fall within the language and the spirit of the Act. When EPA has chosen a wise course in implementing a regulation, or electing not to regulate, we will also commend the Agency and inform the public, which we believe we have done here today. In CMA's judgment, TSCA is a workable law and, if implemented in a fair and reasonable fashion, can provide a sound framework for regulating the health and environmental effects of chemicals. We see no need for TSCA amendments at this time.

We wish to thank the Subcommittee for inviting CMA's comments on EPA's progress in implementing TSCA.

TESTIMONY OF MICHAEL J. SCOTT
GENERAL COUNSEL OF MOONEY CHEMICALS, INC.
CHAIRMAN, TSCA COMMITTEE, SOCMA

Mr. Chairman, and distinguished members of this Subcommittee, I am Michael J. Scott, General Counsel of Mooney Chemicals, Inc. which is a small manufacturer of specialty chemicals based in Cleveland, Ohio. I appear today on behalf of the Synthetic Organic Chemical Manufacturers Association, Inc. ("SOCMA") whose TSCA Committee I chair. I want to thank the Subcommittee for this opportunity to present the views of SOCMA and its member companies on the implementation of the Toxic Substances Control Act ("TSCA").

SOCMA is a non-profit trade association representing over 100 organic chemical companies, the majority of which are small companies with annual sales under \$50,000,000. The members of SOCMA produce more than 5,000 distinct synthetic organic products which are primarily intermediates and finished chemicals for industrial use. A list of the member companies is attached as Appendix A.

The implementation of TSCA has already and will continue to have a significant impact on the chemical industry in general and on small chemical companies in particular. My testimony will address five areas that are of special concern to SOCMA and its smaller members. These are:

- the adverse impact of TSCA requirements on small business;
- the need for EPA to conduct a comprehensive review of the entire TSCA program to evaluate systematically the many problems it presents to small businesses and to develop an integrated policy to minimize such problems consistent with health and environmental objectives;
- the need for EPA to reduce the burden of pre-manufacture notification ("PMN") requirements on

innovation by small companies and to promulgate a final PMN exemption for certain low volume chemicals, site-limited intermediates and polymers;

- the need for EPA to use a consistent small business exemption in reporting and recordkeeping rules under section 8(a) and, when appropriate, in other reporting and recordkeeping rules under TSCA; and

- the appropriateness of EPA using voluntary test agreements and negotiated regulatory action under TSCA.

I. ADVERSE IMPACT OF TSCA ON SMALL BUSINESS

Small chemical companies are disproportionately impacted by TSCA requirements. They generally produce low volume chemicals in quantities under 10,000 pounds annually which generate insufficient revenues to cover high PMN costs. Similarly, small chemical companies lack the in-house technical staff available to large companies to generate extensive toxicological and environmental information and lack the administrative capability to handle extensive reporting and recordkeeping requirements. Thus, a small company has to divert limited staff resources from essential tasks to comply with many TSCA requirements or hire outside consultants and other personnel.

To survive and prosper, a small company must be able to innovate and respond quickly to the immediate and specialized needs of a customer. However, the overall impact of TSCA has reduced the competitive advantages which small companies with low overhead have over large companies to meet customer needs in a prompt and economical manner. A study by the

Regulatory Research Service for the Chemical Specialty Manufacturers Association ("CSMA") concluded that TSCA requirements have had a substantial adverse impact on innovation as a whole which was "particularly heavy for firms in smaller size classes."^{1/}

II. INTEGRATED POLICY TO MINIMIZE SMALL BUSINESS IMPACTS

In light of the adverse impacts of TSCA on small business, it is imperative for EPA to develop and maintain a continuing awareness of the problems and needs faced by small companies in complying with TSCA requirements. Recently, EPA has taken several commendable measures which address small business problems under various TSCA requirements. These actions have included the appointment of a small business ombudsman in EPA's Office of Management and Policy Review, the issuance of a proposed small business exemption for most reporting and recordkeeping rules under section 8(a), and the publication of a proposed PMN exemption for low volume chemicals and site-limited intermediates. While there has thus been progress on several matters of concern to small business, more needs to be done if small chemical companies are to continue as viable members of the chemical industry.

SOCMA believes that Congress should direct EPA to undertake a comprehensive and systematic evaluation of the

1/ "Impact of the Toxic Substances Control Act on Innovation in the Chemical Specialties Manufacturing Industry" at 3 (Jan. 1982).

problems which the entire TSCA program presents to small business and develop an integrated policy for minimizing these problems consistent with providing adequate protection for human health and the environment. This evaluation should encompass small business impacts under the entire Act in order to identify and evaluate the cumulative impacts presented by it. Too often in the past, EPA has viewed an individual TSCA rulemaking and its impact on small business as being separate and distinct from other rulemakings. A statute-wide perspective is urgently needed. In addition, this evaluation should encompass a broad time perspective so that both past and future small business impacts under the Act are considered.

This TSCA-wide evaluation should cover substantive areas similar to those which the Regulatory Flexibility Act requires agencies to consider in identifying the significant economic impacts of proposed rules on small entities. The study should cover the following areas:

- 1) a profile of small chemical companies subject to TSCA requirements including their size, number of employees, sales revenues, kind of product line, number of new chemicals introduced, ability to absorb regulatory costs, and other relevant information;
- 2) a description of the impacts on small business of compliance with existing and anticipated TSCA requirements, including the impact on innovation, capital formation and health and environmental protection, and a description of the financial, personnel and administrative resources necessary for efficient compliance with such TSCA requirements; and
- 3) an identification of all relevant federal and state rules and programs which may duplicate, overlap or conflict with TSCA requirements.

The information compiled from this evaluation could be used by EPA in future TSCA rulemakings to evaluate both the small business impact presented by a particular proposal and its contribution to the cumulative burden posed by all TSCA requirements.

In light of the impacts identified by the above evaluation, EPA should also develop and utilize certain regulatory options to minimize the adverse impacts of TSCA on small entities. As suggested in the Regulatory Flexibility Act, such options could include:

- 1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
- 2) the clarification, consolidation, or simplification of compliance and reporting requirements for such small entities;
- 3) the use of performance rather than design standards;
- 4) an exemption from coverage of any rule, or any part thereof, for such small entities.

In addition, other options unique to TSCA could be developed, including the expansion of the current outreach program in the TSCA Office of Industry Assistance to include manuals and other informational tools geared strictly to small business, the expansion of certain health and environmental effects research by the Agency which may benefit small businesses, and the general use of negotiated regulatory agreements under TSCA instead of rulemaking proceedings.

An important component of any evaluation of small business is the definition of small business. EPA has used widely varying small business definitions in prior section 8(a) rulemakings. We believe that a consistent small business definition should be finalized for use in evaluating the impact on small business of all TSCA reporting and recordkeeping rules.

Adoption of a comprehensive small business policy would have demonstratable benefits in minimizing the burden and expense of regulatory requirements, in light of the more limited resources available to small companies. As a result, these companies would become more innovative and productive. At the same time, this policy would enhance TSCA enforcement by making regulatory requirements easier to understand and to comply with, thereby permitting company resources to be focused on significant health and environmental concerns. Thus, it would provide substantial benefits to small companies while supporting the health and environmental objectives of TSCA.

III. PREMANUFACTURE NOTIFICATION REQUIREMENTS

PMN requirements in particular have imposed a considerable burden on chemical innovation. A study conducted by the Regulatory Research Service for the Chemical Manufacturers Association ("CMA") estimates that PMN requirements may have reduced new chemical introductions by 71 to 87 percent.^{2/} To

2/ "A Critique of the EPA 'Economic Impact Analysis of Proposed Section 5 Notice Requirements'" at xxxi (Mar. 1981).

lessen this burden, SOCMA believes that EPA should implement the use of a "pay-as-you-go" approach in this area whereby regulatory requirements are consistent with a new chemical's production and exposure potential. Such an approach, through the use of PMN exemptions and other actions, would lessen the financial burden on the chemical industry and encourage technological innovation as required by section 2(b)(3) of TSCA.

A. Current PMN Program

Many chemicals which small companies develop cannot support high PMN costs. These chemicals are typically produced in small volumes in response to an individual customer's needs and generate insufficient revenues (in some cases as little as \$2,000-5,000 annually) to cover such costs.^{3/} While these new chemicals often represent a minor change from a small family of preexisting chemicals produced by the small company, such chemicals nevertheless must go through costly PMN review. In addition, small companies lack the personnel and other resources to generate extensive PMN data.

As a result, the present cost of filing a PMN has effectively ruled out the development of many new small chemicals by these companies. Small companies are thus losing their competitive edge over large companies with bigger overhead to

^{3/} EPA and its contractors have estimated that 50 percent of all chemicals are produced in quantities under 10,000 pounds and that 70 percent of all new chemicals are produced in quantities under 10,000 pounds.

produce small volume specialty chemicals for particularized customer needs. A report prepared by the Regulatory Research Service for CSMA found that "the impact of PMN costs falls almost entirely, and heavily, on smaller firms" and this impact has resulted in a significant reduction of new chemical introductions by them.^{4/}

In light of this adverse impact on the operations of small chemical companies, it is imperative that EPA reduce PMN compliance costs to the maximum extent consistent with adequate health and environmental protection. Under the previous Administration, EPA had proposed on January 10, 1979 a very detailed and costly set of PMN regulations and forms for new chemicals. While EPA repoposed a shortened version of the PMN form on October 16, 1979 at the urging of SOCMA, CMA and other chemical industry groups, we still have reservations about many aspects of that repropasal. A Regulatory Research Service study for CMA reveals that the average direct cost of filing PMN on this repoposed form would still be \$12,056 and that indirect costs of \$7,548 would increase the total cost per chemical to nearly \$20,000, exclusive of testing costs which could easily match the cost of filing the repoposed form.^{5/}

4/ "Impact of the Toxic Substances Control Act on Innovation in the Chemical Specialties Manufacturing Industry" at IV-11 (Jan. 1982).

5/ "A Critique of the EPA 'Economic Impact Analysis of Proposed Section 5 Notice Requirements'" at III-66, IV-47 (Mar. 1981).

SOCMA urges that any final PMN rules and forms be significantly less detailed and burdensome than the previous PMN proposal and reproposal. We believe that any PMN forms should track the PMN information required under section 5 as closely as possible. This information which encompasses information on chemical, physical and biological properties, exposure data, and test data is sufficient for the risk assessment type review which Congress contemplated under section 5. We have developed a proposed form which accomplishes this objective and have submitted it to EPA.

While some have questioned the adequacy of PMN data submitted to EPA in the past, extensive PMN information and test data is not required for many new chemicals. Such chemicals are often produced in small quantities for highly controlled industrial uses so that worker exposure is low and consumer exposure is non-existent. Similarly, new chemicals developed by small companies typically involve minor changes in one of a narrow group of closely related preexisting chemicals about which the company has extensive experience. When necessary, small companies have been innovative in utilizing outside expertise, such as the medical staff of a local hospital, to ensure that the health and environmental properties of a new chemical are properly evaluated. Thus, there typically is not a need for conducting an extensive battery of tests in order to make a careful assessment of the risks presented by a new chemical.

We believe that prudent and responsible companies will provide an adequate amount of PMN information and test data, when necessary, for EPA's review. If companies do not submit necessary test data, EPA has more than adequate authority under section 5(e) to take regulatory actions against PMNs with insufficient information. Moreover, EPA has ample authority to track the commercial development of a new chemical after PMN through the use of reporting rules under section 8, significant new use rules under section 5, test rules under section 4 and regulatory action under sections 6 and 7.

B. PMN Exemption

Along with a streamlined PMN process, EPA's issuance of a PMN exemption rule for certain chemicals which do not pose an unreasonable risk under section 5(h)(4) of TSCA would greatly minimize the adverse impact of PMN requirements. As the House Committee on Energy and Commerce recently noted, granting section 5(h)(4) exemptions for certain chemical groups is "important from the standpoint of both agency resources and manufacturer cost." H.R. Rep. No. 97-86 at 7 (May 19, 1981). The Report concluded: "The Committee finds that the Agency could allay many of the concerns regarding the purported adverse effects of Section 5 by expeditiously developing a series of exemptions under Section 5(h)(4)." *Id.* at 8.

In response to this Congressional directive and petitions from CMA, SOCMA and others, EPA recently issued a proposed PMN exemption for certain low volume chemicals, site

limited intermediates and polymers. This proposal would grant a PMN exemption to chemicals produced in quantities between 1,000 and 10,000 kilograms per year and site-limited intermediates if a qualified expert determined that the new chemical does not present a carcinogenic or teratogenic risk and, under its conditions of production and use, does not present other significant health or environmental risks. The proposal also provides a very low volume tier which would exempt chemicals under 1,000 kilograms per year if the company could certify, after its own review, that the chemical would not present significant health or environmental risks under its conditions of production and use. In all cases, a manufacturer seeking a PMN exemption would have to submit a notice of such exemption to EPA at least 14 days prior to manufacture of the new chemical so that the Agency could conduct its own review. If at some later time, a manufacturer wanted to exceed the 10,000 kilograms per year limit of the low volume PMN exemption or use a site-limited intermediate in a non-exempt manner, a full blown PMN submission would be required before doing so.

EPA is to be commended for its efforts in developing this much needed PMN exemption proposal. It would significantly reduce the cost of PMN requirements for many chemicals and allow small companies to respond to immediate customer needs without a 90 day PMN delay in many cases. Moreover, by focusing the PMN review process on higher volume chemicals, manufacturers of such PMN chemicals would be able to afford to

conduct more toxicological and environmental testing to obtain more test data. Where a chemical has completed a period of commercial production during the exemption period prior to filing the PMN, the manufacturer will also have a better understanding of the commercial application and the exposure potential which may exist. This approximates the "pay as you go" approach that SOCMA has urged EPA to adopt in its comments on the PMN rules and forms.

At the same time, SOCMA firmly believes that the contemplated PMN exemption would provide more than adequate protection against chemicals which may present an unreasonable risk to health and the environment. Because of the low volume nature of an eligible chemical and the site-limited nature of an eligible intermediate, virtually all exempted chemicals will not present significant exposure to health or the environment. Furthermore, the automatic exclusion for carcinogenic or teratogenic effects, the qualified expert review, and the 14 day review by EPA would ensure that chemicals with health and environmental concerns are identified. Thus, adequate safeguards are provided to ensure that both exposure and toxicity aspects of the new chemical are adequately evaluated and controlled.

In addition, SOCMA strongly supports the abbreviated PMN exemption process in the proposal for very low volume chemicals produced in quantities of 1,000 kilograms per year or less. For a PMN exemption to be beneficial to small companies, the cost and complexity of qualifying for it must be kept to a

minimum. Often these companies make very low volume chemicals for sophisticated industrial customers which generate only \$2,000-\$5,000 in annual revenues. By allowing a company to rely on an in-house staff review to certify that the PMN exemption requirements for very low volume chemicals are satisfied, this PMN exemption tier would eliminate the need for small companies to hire expensive toxicologists and other professional consultants to conduct the qualified expert review required for the other proposed exemption categories. Yet, company personnel would be capable of undertaking the review necessary for the exemption certification based on their intimate knowledge of the low exposure conditions involved and their familiarity with the narrow range of chemicals from which the very low volume chemical typically emanates. Thus, this very low volume tier would provide significant relief for small chemical companies while ensuring that the health and environmental attributes of the new chemical have been adequately reviewed.

IV. SMALL BUSINESS DEFINITION IN TSCA RULES

In the past, one of SOCMA's major concerns with EPA's implementation of TSCA has been the narrow, rule by rule manner in which the Agency has defined small business for purposes of the small business exemption from routine reporting and recordkeeping requirements under section 8(a). This ad hoc approach, which has included a small business definition as low as \$500,000 in annual sales, has created much uncertainty about whether a company is considered small for a particular rule and

has required companies to check each individual rule. Moreover, the rule by rule approach has ignored the significant cumulative impact that reporting rules can have on small companies. Filling out complex government forms is a time consuming and difficult task for small companies which lack the administrative and personnel capabilities to take care of such matters. For these reasons, the House Committee report for the 1980 TSCA authorization bill directed the Agency "to pursue promulgation of [a small business definition] with all necessary speed." H. Rep. No. 96-968 at 6-7.

Recently, EPA has issued a proposed definition of small manufacturers for use in most section 8(a) reporting and recordkeeping rules. SOCMA believes that this proposal for a consistent small business definition represents an important step to simplify the burden of complying with section 8(a) rules. We also believe that this small business definition should be used to provide an exemption for small business from other TSCA reporting and recordkeeping rules. The use of such exemption needs to be an integral part of EPA's overall policy of minimizing the impact of TSCA requirements on small companies.

Under EPA's proposed small business definition, section 8(a) rules would not apply to (1) manufacturers having less than \$30 million in annual sales of a chemical subject to the rule, provided they produce annually less than 100,000 pounds of the chemical at any one site, and (2) all

manufacturers having less than \$3 million in annual sales, regardless of production volume. We believe that the sales levels in this proposal need to be reviewed and that the final small business rule should provide for the automatic annual adjustment of these levels to account for inflation.

While other reporting and recordkeeping provisions under section 8 of TSCA do not specifically provide for a small business exemption, SOCMA believes that the use of such an exemption should be considered in connection with all TSCA rules. We believe that a small business exemption is appropriate whenever the burden of these rules on small companies outweighs the likelihood that such rules will generate significant health or environmental information which is unavailable from other sources.

The use of a small business exemption in other TSCA rules is consistent with the requirement of the Regulatory Flexibility Act that before an agency issues a rule it must consider whether there are regulatory alternatives to minimize the small business impacts of the rule consistent with statutory objectives. At the same time, we are not suggesting that EPA should provide a small business exemption where, for example, the burden of the rule is low and the informational need is great such as in certain reporting rules for a chemical subject to a test rule or regulatory action.

Under the previous Administration, EPA issued a broad and burdensome reporting proposal for health and safety studies

under section 8(d) of TSCA which was unlikely to yield new health and safety studies from small companies. While this regulation, as proposed, definitely needed a small business exemption, we understand that EPA has narrowed the scope of the proposal and thus may have eliminated the need for a small business exemption in the final rule. However, we remain concerned that future section 8(d) rules may be more burdensome and urge EPA to seriously consider the use of a small business exemption in them.

Under other circumstances, statutory objectives may not be best served by a small business exemption. For example, EPA is developing a final rule for the recordkeeping of significant adverse reactions under section 8(c) where a distinction between large and small businesses may not be appropriate. We are thus in favor of a balanced consideration of small business needs in conformance with the environmental and health objectives of the statute.

V. VOLUNTARY TESTING AGREEMENTS AND NEGOTIATED REGULATION

SOCMA believes the use of negotiated agreements between EPA and industry to achieve voluntary industry action or compliance under TSCA is a flexible and intelligent approach to regulation. This approach is attractive to small business because it can result in requirements more tailored to an individual situation, thereby making them less costly, and it avoids the expense of participating in formalized rulemaking proceedings. At the same time, voluntary agreements can often

be obtained in much less time than going through extensive and time-consuming rulemakings. We believe that negotiated agreements are particularly appropriate in situations involving possible test rules under section 4 and possible regulatory action under section 6.

In response to test recommendations by the Interagency Testing Committee under section 4 of TSCA, EPA has entered into or is currently negotiating voluntary test agreements with industry groups in lieu of issuing a formal section 4 test rule. This approach has allowed necessary testing to begin in a much shorter time than would occur if a full blown rulemaking proceeding were required under section 4. Prior to the use of negotiated test agreements, EPA had been unable to issue any final section 4 (a) rules. In addition, a negotiated test agreement frees Agency resources and personnel to address more significant health and environmental concerns in other areas.

At the same time, a number of incentives are presented to ensure that the voluntary test agreements are adhered to and that the testing proceeds on schedule. Industry would have nothing to gain by breaching such an agreement because the Agency retains the authority to issue a formal section 4 test rule. Adequate precautions, such as interim reports and EPA inspection of the test facility and test data generated, are available to ensure that the voluntarily conducted tests were in accordance with the required GLPs and other protocols.

SOCMA also believes that such a voluntary approach could be used effectively with respect to potential regulatory action under section 6. Under this approach, chemical manufacturers and processors could enter voluntary agreements with EPA to impose certain conditions on the production, use or exposure of a chemical for which there is strong concern about whether it presents an unreasonable risk. This voluntary approach would achieve health and environmental protection in much less time than promulgating a section 6 rule.

VI. CONCLUSION

In summary, I have pointed out the need for EPA to develop an integrated approach to implementing TSCA which adequately considers its cumulative impact on small business. While EPA has taken a fresh look at the Act in certain areas that impact small companies, a more comprehensive approach with small business needs in mind is required.

Again, I thank you for the opportunity to present the views of SOCMA on the oversight of TSCA. I would be pleased to answer any questions that you have.

SOCMA MEMBERSHIP

ACETO INDUSTRIAL CHEMICAL CORP.
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ALLIED CORP.
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AMERICAN CYANAMID CO.
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NEW CHEMICALS PROGRAM

Excerpted from:

Priorities for OTS Operation

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**Office of Toxic Substances
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CHAPTER III -- NEW CHEMICALS PROGRAMA. Introduction

This chapter describes OTS's overall approach under TSCA to new chemicals. In developing this approach, OTS has focused not simply on premanufacture notice (PMN) requirements; it has also considered other elements important in a comprehensive new chemicals program. The program reflects a balancing of the following elements:

- (1) Review of PMN's. The review of PMN's will be accorded high priority. Subjecting new chemicals to meaningful review is essential to ensure that risks associated with new chemicals are adequately characterized and, where necessary, controlled.
- (2) PMN requirements. PMN submitters will be required to provide only the information specified in the Act. This should be sufficient for review of the vast majority of PMN's. When more information is needed, OTS will seek it on a voluntary basis. If the information is not provided, OTS will issue section 5(e) orders to obtain it. The Office will use section 5(e) flexibly, so that incentives are provided for industry to characterize risks better.
- (3) Exemptions. By developing exemptions for low risk chemicals from PMN requirements, OTS will minimize PMN costs without significantly increasing risks to health and the environment. Exemptions will also allow EPA to focus its resources on new chemicals of potential concern.
- (4) Followup of new chemicals. OTS's followup program will place a bound on the risks associated with new chemicals. Judicious use of section 5(a)(2) significant new use rules supplemented by section 8 information gathering will provide important protection against risks associated with new chemicals after commercialization with minimal burdens on industry.

In implementing an effective new chemicals program, OTS will fully integrate each of these elements into a coordinated overall approach. Any changes in one element of this approach will be examined for potential impacts on other elements.

B. Background

Congress instructed EPA to address risks posed by new chemicals before commercialization and therefore to protect human health and the environment from unreasonable risks before damage occurs. As the TSCA Conference Report states:

The most desirable time to determine health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized. (TSCA Legislative History, p. 678).

However, the law also requires that the Agency be careful not to impede innovation and the development of new products unreasonably.

Congress authorized EPA to review new chemicals in section 5 of the Act, which states that manufacturers must notify EPA at least ninety days before they make a new chemical. In EPA's premanufacture review program, which has been in operation since July 1979, the Agency has reviewed over 1,000 PMN's. This program has had some good results: A competent scientific staff has been assembled to review PMN's; methodologies for predicting potential risks, given limited technical data, have been developed, although further refinements are needed; and EPA dealings with industry and other members of the public have been effective -- communications are open and informal rather than highly bureaucratic. The Agency has generally been able to persuade manufacturers to adopt voluntary measures to control exposure when it has identified specific concerns; section 5(e) orders have been issued only when the voluntary approach has failed. Most important, EPA has identified and prevented or reduced risks to health and the environment that might have been posed by a significant number of new chemicals. Several PMN's have been withdrawn during the review period as a result of EPA concerns, and in approximately sixty cases manufacturers have agreed to develop further data or institute exposure controls at EPA's suggestion.

In its experience with the PMN program to date, OTS has been able to make the following observations:

- o Relatively few data are submitted on new chemical substances. This is due, in part, to a perception on the part of the regulated community that most PMN chemicals are not intrinsically hazardous. The degree to which this may be an accurate perception is perhaps best addressed in considering an exemptions policy.

- o EPA has had some concern about a number of other new chemicals and has successfully negotiated voluntary controls or further data for approximately sixty.
- o Only a small number of new chemicals have warranted formal action. Nine PMN's have been subject to section 5(e) orders, and several others were withdrawn before a section 5(e) order was prepared. All of these orders were based primarily on the "may present" rather than the "substantial exposure" finding. No section 5(f) orders have been issued.
- o Relatively few PMN chemicals have gone into commerce. (EPA has received Commencement of Manufacture Notices on only about one third of the chemicals that have completed PMN review.)
- o New chemical substances are produced in relatively low volumes. Twenty-five percent of PMN chemicals have projected third-year volumes below 11,000 kg. Only 15 percent have projected third-year volumes in excess of 1,000,000 kg.
- o PMN's contain only early projections of a chemical's eventual production volume and uses; therefore, they provide limited information concerning the circumstances that will actually develop once the chemical is commercialized.

These facts suggest that, despite its successes, the PMN program as it is now conducted is not completely adjusted to the realities of commercial chemical development. On the one hand, many new chemicals of low concern may be subject to notice requirements unnecessarily; on the other hand, new chemicals potentially of concern but not warranting action early in commercial development may now enter commerce without any subsequent EPA review.

To date, OTS has concentrated on developing an effective process for reviewing PMN's. The Office will continue to refine this process, both by focusing the initial information requirements it has proposed for PMN's and by emphasizing voluntary means and the use of section 5(e) to obtain further information, where necessary. OTS will also develop rules under other sections of TSCA to complement the PMN review program and to establish a comprehensive new chemicals program. Specifically, it will exempt certain categories of low risk chemicals under section 5(h)(4), and it will develop followup rules on chemicals of concern under sections 5(a)(2) and 8(a). In this way, OTS will ensure that Agency resources are focused on new chemicals of concern, while burdens on industry are minimized.

The remainder of this chapter describes OTS's overall approach to new chemicals.

C. Review of PMN's

The review of PMN's will continue to be accorded a high priority within OTS. Although industry has made strides in protecting health and the environment, a credible PMN program, subjecting new chemicals to meaningful review, is needed to ensure that risks associated with these chemicals are adequately characterized and, where necessary, controlled.

1. Factors of concern in review. OTS has developed several basic principles in the PMN program for reviewing new chemicals and allocating resources:

- o The PMN review addresses the entire life cycle of new chemicals (that is, no part of the life cycle of new chemicals is routinely excluded). Therefore, occupational exposure; releases to air, water, and land; and consumer exposure are reviewed to determine if they raise a potential concern. Congress clearly intended the PMN review to take this broad approach.
- o The review focuses on the new chemical itself as it will be manufactured (i.e., including reasonably anticipated impurities). The program provides only a limited evaluation of the byproducts of manufacture and processing and focuses to the greatest extent on byproducts of use.
- o The review focuses on chronic or irreversible effects. Such effects may typically manifest themselves even at low exposure; in addition, because there may be a long latency period, such exposures are often not recognized at the time they occur. Acute effects are more immediately obvious and more generally controlled. Nevertheless, acute effects are considered when potential toxicity is severe, particularly if the exposed population is not likely to be aware of potential hazards.
- o Both human health and environmental effects are addressed in PMN review. However, the emphasis of the review is on human health risks. OTS has adopted this approach in part because the relatively low production volume and release levels of new chemicals tend to limit environmental concentrations and therefore risk. In addition, environmental assessment methodologies are not as well developed as methodologies for assessing human health risks, and the data base is not as extensive. Nevertheless, in spite of these factors, OTS is continuing to develop its environmental assessment capabilities and will take action where significant environmental risks are identified (such as significant impacts on fish populations).

- o Potential risks must be assessed at least in part through structure-activity analyses -- that is, the toxicity of new chemical substances is estimated from their structural similarity to chemicals of known toxicity. This has been necessary in part because of the sparsity of test data on the new chemicals themselves. Although conclusions drawn on the basis of structure-activity analyses must be tentative, there is a great deal of evidence to support the usefulness of this approach when conducted by trained toxicologists and chemists with broad expertise.

2. Data development on new chemicals. Congress did not require testing of new chemicals under section 5. Instead, EPA is given the authority under section 5(e) to require testing of specific new chemicals when it can make the appropriate finding.

OTS's experience with the PMN program indicates that relatively limited health and environmental-effects testing is performed on new chemicals prior to PMN submission. There are several reasons for the sparsity of test data in PMN's. First, many new chemicals do not warrant testing: some belong to chemical classes the biological activity of which is already well characterized; others are produced in low volume or used in ways that lead to limited exposure (e.g., site-limited intermediates). Second, because new chemicals are early in commercialization, they often cannot support the costs of extensive testing. Third, many manufacturers traditionally have not done testing at this stage in a chemical's development, even when it was economically feasible. Finally, manufacturers may be reluctant to create and provide the government with information because of a fear that the government will act precipitously in response to positive data.

Limitations in data, however, in some cases limits EPA's ability to review risks. OTS is structuring the new chemicals program so that essential data can be developed when needed. The Office has two basic tools for achieving this end. The first is the significant new use and section 5(e) authorities. The judicious use of these authorities can allow for the tracking of chemicals of concern so that risks can be managed over the commercial life of the chemical. The second tool is the information-gathering authority of section 8. As described later, these authorities will be used to construct a new chemicals followup program for chemicals of concern that will allow EPA to review data at a later stage of commercialization.

In addition to using these formal mechanisms, OTS will continue to work with individual PMN submitters to encourage the development of needed data on a voluntary basis. In the past, OTS and industry have been able to resolve important uncertainties through such a voluntary approach.

The Organization for Economic Cooperation and Development (OECD), a multinational group including the United States, has adopted a set of uniform guidelines for testing the health and environmental effects of chemicals. Where manufacturers elect to conduct tests on new chemicals, either in support of a PMN or in response to a section 5(e) order, OTS encourages them to consider these guidelines. In addition, the OECD is considering the adoption of a Minimum Premarket Data (MPD) set recommended for new chemicals entering the commercial market. The information provided by this data set is frequently useful in assessing risks posed by such chemicals and in identifying areas where further testing should be conducted. TSCA, however, does not require across-the-board testing of new chemicals. PMN experience confirms that rigid testing schemes for these chemicals are inappropriate -- in some cases, all the MPD data are not necessary; in other cases, other chemical properties should be assessed. Therefore, as the OECD recognizes, manufacturers should use judgment in determining which tests should be conducted on a specific new chemical. They should base this decision on such factors as chemical identity, production volume, intended uses, and likely exposure.

3. Actions under section 5. Although PMN submitters have generally provided relatively limited health and environmental effects data, OTS has taken few actions under section 5(e) to require the development of additional data.* This situation reflects four facts. First, the limited production volume and uses of most new chemicals generally lead to low exposure and consequently low risk. Second, OTS has taken the position that the section 5(e) "may present" finding must at a minimum be supported by test data or by a strong structure-activity case (e.g., that the new chemical is a close analog of substances of known biological activity). Third, OTS has focused primarily on the use of section 5(e) to gather test data rather than to gather other information necessary for a reasoned evaluation of risks posed by a new chemical. Finally, the Office has not considered taking section 5(e) action on new chemicals because of substantial exposure without specific concerns for potential toxicity.

* Section 5(e) authorizes EPA to regulate a new chemical, pending the development of information, in the absence of information sufficient "to permit a reasoned evaluation of the health and environmental effects" of the substance if it makes the finding that the substance "may present an unreasonable risk of injury to health or the environment," or that the substance "is or will be produced in substantial quantities" and "either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance."

In the future, OTS will use the section 5(e) authority more flexibly. For example, if the circumstances of early commercialization limit the risks from a new chemical, but the standards for section 5(e) actions are otherwise met, the use of a "delayed trigger" section 5(e) order would allow the chemical to enter commerce. Data submission would be required later, either after a certain number of years or after a specified cumulative production volume had been reached. The decision to use a delayed-trigger section 5(e) order or an immediately effective order will depend on the potential risks and the commercial future of the new chemical. Where the magnitude of the potential risk and the level of certainty that such risks will occur is high, OTS will continue to impose immediate controls. However, where the risks are limited or where there is less certainty, it is reasonable to allow limited commercialization and to provide for data submission at a later time, when the costs associated with testing would be less, compared with sales volume, and when manufacturers would have greater certainty of the chemical's commercial potential.

OTS will also use section 5(e) more broadly to obtain exposure and release information (as well as toxicity test data) needed to make a reasoned evaluation of new chemicals. Industry has often suggested that EPA use section 5(e) for this purpose.

Finally, OTS is placing more emphasis on the use of section 5(e) in cases of "substantial exposure" where there is some basis for concern. The Office has adopted the policy that, where production volume and exposure are high, section 5(e) will be invoked if there is significant uncertainty concerning the effects of a chemical; in this way, OTS will use section 5(e) to ensure that risks of new high-volume chemicals are adequately characterized. This approach is especially justified because high volume chemicals are better able to withstand the greater costs of characterizing risks.

After reviewing nearly 1,000 PMN's, OTS has not yet seriously considered issuing a section 5(f) order.* The reason for this is clear: few if any new chemicals are sufficiently characterized to support a finding that they "will present" an unreasonable risk. It is much easier to make the "may present" or "substantial exposure" finding of section 5(e). Therefore, the section 5(e) authority can be more readily used to control risks from new chemicals. Also, where risks are so evident as to warrant action under section 5(f), they will typically be identified by the manufacturer. In this case, the risks will be

* If EPA finds "that there is a reasonable basis to conclude" that a new chemical substance presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6 can protect against such risk," the Agency can regulate the substance under Section 5(f).

adequately controlled or no notice will be submitted. For these reasons, it appears that section 5(f) is a practical regulatory tool only in special circumstances. In the event that a section 5(f) issue arises, it would be handled on an ad hoc basis.

4. Relative risk ("me-too" issue). Many new chemical substances present risks comparable to risks presented by structurally similar existing chemicals. In reviewing new chemicals, OTS considers these comparative risks. For example, when a new chemical of concern would substitute for a chemical of greater concern, the Office has generally declined to take action on the theory that it should not do anything to discourage substitutions that would lead to a significant reduction in risk. It has also been argued that EPA should not take action against a new chemical if existing substitutes present comparable risks. OTS has generally rejected this approach: It is Office policy that the Agency should not refrain from regulatory action against a new chemical simply because risks posed by the new chemical were likely to be comparable to risks from similar chemicals already on the market. Thus, OTS has rejected the "me-too" approach to new chemical regulation.

The rationale for OTS's approach is two-fold: (1) Congress intended that EPA subject new chemicals to a higher standard than existing chemicals, and (2) OTS should discourage innovation in classes of chemicals of known concern without the development of adequate data. This policy must be applied flexibly. In circumstances where chemicals provide significant benefits, EPA should not take action in cases of comparable risk. In general, however, the rejection of the "me-too" principle is essential for a viable new chemicals program. Most potential actions under section 5 will raise questions of comparable risk because new chemicals are typically modifications of existing substances. If actions were not taken in such circumstances, EPA's authority under section 5 would be seriously compromised. This would clearly contradict Congress's intent that EPA treat new and existing chemicals differently.

D. PMN Rule

The major purpose of a PMN rule would be to tell the public what information must be submitted as part of a premanufacture notice. The proposed PMN rule and forms, which appeared in the Federal Register of January 10 and October 16, 1979, are controversial. Industry generally views the rule as overly burdensome and argues that submitters would be required to go through the expense of providing information that is generally not needed to review PMN's. In addition, many commenters argued that EPA overreached its authority in interpreting the Act's requirements. On the other hand, some environmental and labor groups have stated that the proposed rule would not provide EPA with enough information to perform an adequate review.

It is clear that the form repropoed on October 16 is imposing, even though it is considerably simpler than the January 10 form. OTS has also learned, after two and a half years of experience with reviewing PMN's, that much of the information required in the latest proposal is not, in fact, needed for the review of most notices. Therefore, OTS now believes that the information requirements should be further focused and that submitters should be required to provide only the minimum specified in section 5(d)(1) of the Act, which references the information required in section 8(a)(2)(A-G) except (E):

- (A) The common trade name, chemical identity, and molecular structure
- (B) The proposed categories of use
- (C) Estimates of the total amount of the substance to be manufactured and of the amount to be manufactured for each proposed category of use
- (D) A description of byproducts of manufacture, processing, use, and disposal of the substance
- (F) Estimates of the number of individuals who will be exposed in their places of employment, and the duration of such exposure
- (G) The manner and method of disposal.

Given this general list of information requirements, two specific questions remain: (1) How should these information requirements be interpreted? (In other words, what information, specifically, should submitters be required to provide?) and (2) Should EPA publish a mandatory form, which submitters would be required to use?

1. Information requirements. As with most statutory provisions, the information requirements listed in section 5(d)(1) are subject to different interpretations. The proposed PMN rule represents an expansive interpretation. OTS is now adopting a narrower interpretation. Information that is clearly specified in section 8(a)(2)(A-G) except (E) must be required. In addition, information that is essential for the review of most PMN's and that reasonably falls within the intent of section 5(d)(1) will also be required. Other information would be optional.

OTS will still have means at its disposal to gather information for the minority of PMN chemicals on which further information is required to make a reasoned evaluation. Informal requests to the PMN submitter have generally in the past proved adequate to secure needed information; OTS will rely increasingly on this mechanism. Nevertheless, there may still be

circumstances under which a submitter refuses essential information. If this occurs, OTS will issue a section 5(e) order if the necessary findings can be made.

2. Mandatory form. OTS intends to require PMN submitters to complete a simplified form. The form will be easy to fill out so that burdens on the submitter are minimized. It will establish a uniform standard providing submitters a clear idea of what is expected of them; it should make it easier to familiarize submitters with PMN data requirements. In addition, the form would facilitate OTS review of PMN's and the computerization of the information submitted in the notices.

E. Exemptions

As previously stated, many new chemicals present little risk and do not warrant full-scale PMN review early in commercialization. Requiring a PMN on these chemicals imposes a burden with relatively few if any health or environmental benefits. A carefully designed exemption policy under section 5(h)(4) will eliminate much of this burden without significantly increasing risk to human health or the environment.

A section 5(h)(4) exemption, to be usable, must be structured so that it exempts categories of chemicals. OTS experience in its section 4 test program and elsewhere indicates that it is a difficult and controversial task to make findings on categories of chemical substances. Defining classes of chemicals that "will not present an unreasonable risk" may be equally difficult. However, OTS does not expect to achieve a fail-safe system; its goal instead is to develop exemptions that will provide reasonable assurances that exempted chemicals will not present such a risk.

In a recent petition, the Chemical Manufacturers Association (CMA) identified polymers, site-limited intermediates, and low-volume chemicals as candidates for a section 5(h)(4) exemption. The CMA approach follows two general lines of reasoning. First, polymers represent a class of substances that have intrinsically low levels of biological activity. Thus, the finding of no unreasonable risk could in this case be made primarily on the basis of inherent toxicological properties; the finding would not depend on conditions of use. As a result, it would not be necessary for EPA to review the specific properties or uses of exempt polymers before they were manufactured. On the other hand, low-volume chemicals and site-limited intermediates are not intrinsically limited in potential toxicity; instead, they are characterized by limited exposure. For this reason, CMA has suggested that chemicals in these classes be eligible for exemption only after a "qualified expert" employed by the manufacturer establishes that the chemical is not hazardous under the conditions of use. In addition, the exemption would provide for an abbreviated OTS review, based on the submission of minimal data.

Review by an industry "qualified expert" may compensate for the absence of toxicity restrictions for these exempt chemicals. However, an acceptable definition of "qualified expert" and standards for a minimal risk assessment will be very difficult to develop. While OTS is making progress in this area, a qualified expert provision is unlikely, by itself, to ensure that no unreasonable risk may occur. Therefore, it is essential that EPA subject each exempt site-limited intermediate and low-volume chemical to an abbreviated review, perhaps before manufacture begins under the exemption.

An important issue to be resolved is the amount of information that would be required in an exemption notice. If exemption notices are burdensome, exemptions will not be used; however, OTS will need enough information to be reasonably sure that a chemical is eligible for the exemption. OTS is considering this fact in defining its information needs.

As a necessary part of the abbreviated review, EPA should have the authority to declare a chemical ineligible for the exemption if it determines that the chemical may present an unreasonable risk. Although industry has expressed concerns that such authority will add considerable uncertainty to the exemption process, manufacturers will in fact have a high degree of certainty that EPA will rarely declare a chemical ineligible. This is because (a) the exemption already defines a low-risk category, (b) the qualified expert will have assessed the chemical and certified that it is eligible for the exemption, and (c) the "may present" standard will ensure that only chemicals of real concern are excluded. CMA originally suggested a very different approach; under the terms of the CMA petition, EPA would be able to act against an exempt chemical only if it could demonstrate an imminent hazard under section 7. Because OTS has not yet seen a new chemical that met the standards for a section 5(f) order, it seems implausible that a new chemical to be manufactured under the terms of the exemption would meet the criteria for action under section 7.

CMA has suggested and OTS believes that it is important that exempt chemicals not be placed on the TSCA Inventory. This will go a long way toward solving a major problem with the PMN program as it now operates. Under the current system, EPA receives notices on many new chemicals whose toxicity is sufficiently characterized for their proposed conditions of manufacture and use (e.g., many site-limited intermediates and low-volume chemicals). However, the toxicity of these chemicals may not be sufficiently characterized for uses that involve more exposure. Under the current program, these chemicals are added to the Inventory after commercial production begins. At this point, they may be produced in any volume and for any uses without restriction or prior EPA review. If, on the other hand, these chemicals were exempt from PMN notice for low-exposure uses and were not added to the Inventory, they would be subject to notification before manufacture for nonexempt uses. In this way,

EPA would receive a PMN at a point in the chemical's commercial development when it could expect risks associated with the new chemical to be characterized more fully.

F. Followup*

EPA's review of chemicals at the premanufacture stage must focus on the intended methods of manufacture and use described in the PMN, and it is based on toxicity data that the manufacturer has developed before commercialization. After a new chemical is entered on the Inventory, however, unrestricted commercialization is possible (in the absence of a significant new use rule) without further data development or EPA review. Thus the PMN review addresses an extremely narrow segment of the risks that may eventually be posed by new chemicals. For this reason, a credible followup program is an essential element of the new chemicals review program.

Followup will be based on several principles derived from OTS experience in the PMN review program. These principles are described below.

- o Most new chemicals will not be subject to followup rules. Followup will be focused instead on chemicals of concern and substances for which there is significant uncertainty concerning toxic effects. (This is particularly true for followup under significant new use rules.)
- o Most new chemicals do not become established in the marketplace and few grow to significant production volume (indeed, the production volume of a high percentage of existing Inventory chemicals is below 50,000 kg a year). Therefore, EPA will complement the PMN review by later review of certain chemicals that achieve commercial success.
- o Because of the cost of testing and limited exposure early in commercial development, extensive testing may be more appropriate later in a chemical's commercial development. If EPA does not follow up new chemicals of concern, data necessary to characterize risks posed by these chemicals later in their commercial development in many cases may not be developed.

The followup of new chemicals will rest primarily on sections 5(a)(2) and 8(a). The following sections explain how these authorities will be used.

* The appendix to this chapter explains in more detail OTS's program for followup of new chemicals.

1. Significant new use rules. OTS will issue SNUR's on new chemicals where it has significant concern about possible new uses of a chemical or class of chemicals, where it believes those uses reasonably may occur, and where review under section 5 is necessary to protect health and the environment against unreasonable risk before it occurs. Examples of a new use might be: (a) reaching a designated production volume, (b) a new consumer exposure, and (c) uses inconsistent with controls required in a section 5(e) order that does not ban production of a new chemical.

2. Section 8(a) information-gathering authority. OTS will also implement the section 8(a) authority to gather information on selected new chemicals after they have entered commercial development. This will allow OTS to identify risks posed by new chemicals of concern after they have entered commercial production but early in their commercial development. Formal action in response to information received under section 8(a) must be taken under other authorities of the act (e.g., sections 5(a)(2), 4 and 6). OTS's priorities for action on chemicals under these authorities will be independent of its priorities for action on fully commercialized chemicals on the Initial Inventory.

To achieve these ends, OTS will issue chemical-specific, volume-triggered section 8(a) reporting rules on new chemicals of significant concern. The Office has rejected a generic approach to section 8(a) followup of new chemicals. It will require followup reporting only where it has identified specific concerns.

Section 8(a) followup rules will focus on gathering information on production volume and use and will be structured so as to impose a minimum reporting burden on submitters. The information reported under this rule will allow OTS to target its resources on recently commercialized chemicals of concern. Since information requirements will be limited, the burden of the rule will not be great. When information is provided, OTS will be in a position to decide whether action is appropriate, such as the encouragement of voluntary testing, requirement of testing under section 4, issuance of a SNUR, referral of the information to another agency for possible action, or regulation of the chemical.

APPENDIX IIIAFOLLOWUP OF NEW CHEMICALSI. Importance of a New Chemicals Followup Program

The Office of Toxic Substances states in chapter III that a credible followup program is a critical part of any new chemicals program. At the premanufacture stage, EPA's review of chemicals focuses on the intended methods of manufacture and use described in the PMN, and decisions must often be made in the absence of extensive toxicity data. After a new chemical has been entered on the Inventory, however, unrestricted commercialization is possible without further data development or EPA review. Therefore, as a complement to the PMN review program, OTS is instituting a new chemicals followup program designed to reduce possible risks from recently commercialized new chemicals and to encourage data development on these chemicals later in its commercialization.

This followup program will consist of two elements. OTS will develop significant new use rules (SNUR's) under section 5(a)(2) on specific new chemicals when it identifies new uses of sufficient concern. OTS will also use chemical-specific section 8(a) reporting rules to track the commercial growth of selected new chemicals of concern and effectively to place a bound on risks that can occur from these chemicals without Agency knowledge. If judiciously applied, these authorities will impose a minimal burden on industry, while contributing in an important way to the development of data on new chemicals and the reduction of new chemical risk.

OTS's approach is consistent with the general preventive thrust of TSCA, while reflecting the Congressional directive that EPA should not unduly impede or create unnecessary economic barriers to technological innovation. In discussing the case of vinyl chloride, the Senate Commerce Committee Report stated:

the country has grown extremely reliant on the plastics which are produced from the chemical. In fact, 1 percent of our gross national product is associated with the vinyl chloride industry. Obviously, it is far more difficult to take regulatory action against this chemical now, than it would have been had the dangers been known earlier when alternatives could have been developed and polyvinyl chloride plastics not become such an intrinsic part of our way of life in this country. (TSCA Legislative History, p. 161)

This passage clearly indicates that risks should be characterized early in a chemical's commercialization, before an industry is committed to it and before the costs of regulation would be excessive. The most appropriate time to act to control a hazardous chemical, Congress stated, is before unreasonable risks occur and before heavy costs in jobs and wasted investments would be incurred. This passage does not imply, however, that a chemical must be fully characterized before first manufacture, particularly when the costs of such a characterization would be excessive and exposure would be adequately controlled.

A three-part strategy to promote the development of test data on newly commercialized chemicals is needed. This strategy would modify OTS's current new chemicals program so that it will be closer in line with the realities of new chemicals development.

First, OTS intends to issue a broad section 5(h)(4) rule that will exempt certain low-exposure chemicals from PMN requirements (e.g., low-volume chemicals and site-limited intermediates). If these chemicals were to be commercialized beyond the terms of the exemption, they would be subject to PMN. When PMN's were submitted, OTS would expect data appropriate for the chemicals's potential toxicity, level of commercialization, and uses. Since exempt chemicals would not be placed on the TSCA Chemical Substance Inventory, this approach would in effect institute a followup requirement for new low-volume chemicals and site-limited intermediates. This would eliminate some of the current need for a followup program under sections 5(a)(2) and 8(a).

Second, OTS will continue to rely on section 5(e) during the premanufacture review period to gather data on toxicity and will expand the use of section 5(c) to include information on exposure. In addition, OTS will use "delayed trigger" section 5(e) orders under certain circumstances to promote data development at some later point in a new chemical's commercialization. (See Chapter III for a description of delayed trigger section 5(e) orders.)

With these two policies in place, OTS will receive fewer notices on new chemicals (presumably including more data) and will more frequently request additional data on new chemicals under section 5(e). Even under these circumstances, however, EPA will still receive a number of notices on new chemicals that appear to have potential for significant toxicity, but that do not warrant section 5(e) action because uses and production volume described in the PMN indicate low exposure. In these cases, followup action under section 5(a)(2) or section 8(a) is the most effective way for the Agency to encourage the development of appropriate data later in commercialization, to ensure subsequent Agency review, and to place a bound on risks posed by new chemicals after commercialization.

The use of TSCA authorities to develop such a followup program was clearly anticipated by Congress. Senator Magnuson, Chairman of the Senate Commerce Committee, stated in the Senate consideration of the Conference Report,

the requirement that manufacturing and processing notices be given for significant new uses of chemical substances is extremely important. As chemical substances frequently are not manufactured in large volumes or for a large number of uses initially, the authority to require notification for these substances as uses mount or as volumes increase is extremely important. (TSCA Legislative History, p. 723)

As Congress recognized, EPA's new chemicals program will be seriously limited without a followup program. Without such a program, EPA's ability to act on new chemicals and to require data development will depend entirely on the accident of how the new chemicals are initially described in the PMN and how the PMN submitters intend to use them. For example, if vinyl chloride -- the example from the Legislative History cited above -- were a new chemical, EPA's review under section 5 would be limited to a consideration of the methods of production and the uses described in the premanufacture notice. If EPA refrained from action in the absence of data during the review period because exposure was low in the uses described in the PMN, the chemical could enter full-scale commercial development without any assurance that its potential hazards would be further characterized. A major goal of the new chemicals followup program will be to reduce this potential problem by making it possible for the Agency to review new chemicals of concern after they had been entered on the Inventory but before significant new exposures occurred. To make the program effective, OTS is committing resources not only to the development of followup rules, but also to the review of followup notices and, where necessary, action on chemicals subject to followup.

OTS recognizes that a new chemicals followup program in some respects treats new chemicals after commercialization as different from existing chemicals already on the TSCA Initial Inventory. This approach is appropriate for several reasons:

- o PMN chemicals are in a fundamental sense different from chemicals on the Initial Inventory. Unlike chemicals on the Initial Inventory, they have been subject to EPA review. If a new chemical that has been through PMN review becomes the next PCB or vinyl chloride, this will generally and properly be recognized as a failure of the PMN program. OTS could reduce the possibility of such an occurrence only by

requiring complete toxicological characterization at the PMN stage or by developing a followup program.*

- o The new chemicals program properly addresses the full range of risks a new chemical may present as it grows in the marketplace and uses diversify. Because the PMN review addresses only the risks described in the notice, EPA can protect against risks associated with subsequent commercialization only through a carefully focused followup program.
- o By its nature, the existing chemicals program generally deals with high-volume, high-concern chemicals. For these chemicals, the costs of regulation may be high. However, recently commercialized new chemicals, which have not yet reached maturity in the marketplace, can be controlled with less cost before high levels of risk occur.

For these reasons, a broader approach to new chemicals, including new chemicals followup, is justified. The following principles will guide OTS's new chemicals followup program:

- o EPA will focus its followup activities on chemicals of concern. Followup will not be applied indiscriminately.
- o Followup requires a commitment of resources to developing followup rules, reviewing notices when they are submitted, and acting on the chemicals as appropriate after that review.
- o Followup reporting requirements will be structured so that notice occurs before significant changes in commercialization of the new chemicals, but after the chemicals have achieved a certain level of commercial success. In this way, EPA can act to require the development of data on a substance or to

* CMA endorsed the concept of new chemical followup in its recent report, The First Four Years of the Toxic Substances Control Act (1981). According to this report, "CMA agrees that some appropriate mechanism may properly be developed to keep EPA apprised of significant events in the commercial development of [new] chemicals."

control exposure before benefits (e.g., jobs and investments) would make control actions overly burdensome.

- o While the new chemical followup program will be operated separately from the existing chemicals program, it will not proceed in isolation. In some cases, problems identified in the PMN process (or as a result of new chemical followup) will be part of a larger problem that the Agency may address in the context of the existing chemicals program.

II. Implementation of a Followup Program for New Chemicals

There are two basic authorities under which OTS will issue followup requirement: section 5(a)(2) significant new use rules (SNUR's) and the section 8(a) information gathering authority. SNUR's, because they allow review of new uses under section 5, provide a more effective mechanism for preventing risks and encouraging data development. Section 8(a) rules, while easier to develop, do not provide EPA with an effective review mechanism. (Figure 1 summarizes some of the differences between these two authorities.) For this reason, OTS is developing a followup program that relies primarily on SNUR's for situations of high concern supplemented by section 8(a). In this approach, OTS will issue (1) SNUR's on PMN chemicals for which OTS identifies significant new uses of sufficient concern, and (2) 8(a) rules requiring manufacturers to report minimal information on specific PMN chemicals of concern after commercialization. This program is similar to the followup program recommended in July 1980 by the Conservation Foundation, an industry-environmental advisory group.

As explained below, this program will be structured so that it will impose minimal burdens on industry (both because only chemicals of significant concern will be affected and little information would be required). These burdens should be seen as a tradeoff for reduced information requirements at the time of PMN submission.* Because of this, economic and regulatory impacts of this program will be considered within the context of the new chemicals program as a whole.

* In comments on the proposed PMN forms, CMA couples its argument for a shortened form with a suggest 1 followup program that in many respects would be more extensive than the one suggested here.

FIGURE 1
COMPARISON OF FOLLOWUP AUTHORITIES

Authority	Rulemaking Standard	Applicability	Reporting Trigger	Information Requirements	Review and Control Authority
§8(a)	EPA "reasonably requires" information	Manufacturers and processors; small businesses exempt unless chemical is listed under §5(b)(4)	Any appropriate trigger, for example, production volume or specific time after PMN (e.g., 3 years)	Any of the information listed in §3(a)(2); legislative history indicates that this list is illustrative	No mandatory review; control under general TSCA authorities (e.g., §4, §5(a)(2), §7); voluntary controls
§5(a)(2)	New use will be "significant," considering factors listed in §5(a)(2)(A-D)	Manufacturers and processors; no small business exemption	New use ¹	Same information as PMN; information listed in §8(a)(2), minus (F); test data in possession or control; descriptions of other health and environmental effects data	EPA must review under §5; §5(e) and §5(f) available as well as other TSCA authorities

¹OTIS has interpreted "uses" broadly. The following are examples of a new use: (1) reaching a designated production volume, (2) a new consumer exposure, (3) uses inconsistent with controls required in a §5(e) order that does not ban the production of a chemical. In general, OTIS believes that the notification trigger (i.e., the definition of the new use) should be set at a point where §5(e) action could be possible if a significant new use notice were submitted without further data.

A. Significant New Use Rules

Section 5(a)(2) of TSCA authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule, after considering all relevant factors, including (1) the projected volume of manufacture or processing, (2) the extent to which a use changes the type or form of human or environmental exposure, (3) the extent to which the use will increase the magnitude or duration of human or environmental exposure, and (4) the reasonably anticipated manner or methods of manufacture, processing, distribution in commerce, or disposal. Once a use is determined to be a "significant new use" for a given chemical substance, persons must notify EPA at least 90 days before they manufacture or process the substance for that use. This notice must contain the same information required in a PMN -- i.e., the information listed in section 5(d)(1). (However, OTS would expect that exposure information would relate primarily to exposure associated with the new use.) followup requirement: section 5(a)(2) significant new use rules (SNUR) The SNUR requirement may involve greater cost and more uncertainty to the manufacturer than does the PMN requirement. A SNUR, in effect, puts the manufacturer or processor on notice that a problem may exist with a particular use of a given basic chemical and that risks should be adequately characterized before that use occurs. For this reason, TSCA requires under section 5(g) that, if the Agency does not take action on a SNUR notice, it must publish a notice in the Federal Register stating its reasons for not initiating action.

Because of the notification costs associated with SNUR's, these rules might in some cases serve to inhibit the manufacture or processing of chemicals for new uses designated as "significant." Manufacturers and processors would commercialize a chemical for a significant new use only if they determined that the benefits to be derived from commercialization warranted the development of the data necessary to allay concerns (or if they could successfully demonstrate that exposure in the new use would be lower than anticipated). Such an effect is not only acceptable but also appropriate, since SNUR's will be used only when there is a significant level of concern.

OTS intends to issue SNUR's when: (1) it believes it would have a reasonable basis for section 5(e) action on a new use if additional data were not provided, (2) new uses involving significant exposure are not unlikely, and (3) EPA review before the new use occurs (including the possibility of action under section 5) is in the public interest. Based on OTS's experience with PMN review, it appears that about ten SNUR's would be written a year on new chemicals if these criteria are applied.

As a first step, OTS will select several candidates for SNUR's from among the chemicals that are currently on the "followup queue." OTS has developed this list of approximately 170 chemicals of potential concern during the past two and a half

years of PMN review. Considerable progress has been made in the past few months identifying reasonable followup candidates from the queue. A few chemical-specific SNUR's, chosen on the basis of the criteria listed above, should allay many concerns industry has expressed about how OTS intends to use SNUR's for new chemical followup,* as well as provide important protection to health and the environment. In developing these rules, OTS will have the opportunity to resolve many specific issues associated with SNUR's (e.g., how confidential information should be handled, how "significant new uses" should be defined, etc.).

Although compliance with SNUR requirements will entail a certain burden, there are several steps OTS will take to ensure that this burden will be reasonable. For example, OTS might require notification for a significant new use only after manufacture or processing for that use had reached a certain volume. The production volume that would trigger a notice requirement could be set at a level at which the costs of developing the data would be reasonable, and at which EPA could reasonably act under section 5(e) if data were insufficient. Also, OTS will clearly state the nature of its concern in each SNUR. Manufacturers and processors could then determine what data EPA would view as necessary to allay its concerns on how exposure might be controlled. This could significantly reduce the uncertainty present in the submission of a SNUR notice.

B. Section 8(a) Information Gathering

Section 8(a) grants the Administrator broad authority to require manufacturers, importers, and processors to provide available information to EPA on any TSCA chemicals. This information can include use information, production volume, descriptions of byproducts, health and environmental effects data, exposure information, and disposal information. In issuing a section 8(a) rule, the Administrator need only find that the information is "reasonably required." While this finding is less stringent than the SNUR finding, EPA must still demonstrate sound reasons for requiring information under section 8(a), and the costs of the requirement must be justified, given the anticipated benefits.

Section 8(a) is particularly appropriate for identifying which PMN chemicals of concern are likely to prove commercial

* In particular, industry has expressed concern about the SNUR EPA proposed on November 16, 1980, for the new chemical n-methanesulfonyl-p-toluenesulfonamide (PMN 0016). The approach OTS is now taking differs in many respects from the approach taken in this proposed rule -- which defined "significant new uses" very broadly and did not reflect affirmative toxicity concerns.

successes and for tracking specific new chemicals after manufacture begins. Under section 8(a) rules -- which would be applied only to chemicals of concern -- EPA might require minimal information on production volume and use, as well as available health and environmental effects data. Reporting might be required at a specific production volume or after a certain number of years. Although a section 8(a) rule would not afford the protection of a SNUR (because it would not allow review under section 5), it would effectively signal circumstances of major concern before risks became unreasonable and before a new chemical of concern had grown to a point at which control would present significant economic costs.

C. EPA Action on Followup Chemicals

An important distinction between followup under section 5(a)(2) and 8(a) is that, under section 5(a)(2), EPA is required to review the notice, and it has the authorities of sections 5(e) and 5(f) available to require further data on the chemical or to regulate the chemical in its proposed new use. In addition, as mentioned previously, under section 5(g), if EPA does not take action during the review period, it must publish a notice in the Federal Register stating its reasons for not taking action.

Under section 8(a), EPA review is not required, and the Agency does not have the special authorities of sections 5(e) and 5(f). EPA, however, will have the full range of TSCA authorities available to it to control risks identified as a result of section 8(a) followup. These include section 4 test rules (and voluntary approaches to data development in lieu of a section 4 rule), section 5(a)(2) significant new use rules, voluntary controls by the manufacturer or processor, referral to another office or agency, and control under section 6. These authorities should be easier to use as part of a new chemicals followup program than they have proved for fully commercialized chemicals because the chemicals will be relatively early in commercial development. Therefore, costs associated with regulation will be lower, and industry will have greater flexibility in developing controls or in turning to alternative chemicals, if necessary.

Relatively few reports are likely to be received under the new chemicals followup program. Therefore, limited resources will be necessary to ensure an effective program. The Office is also adopting the principle that regulatory or other action against recently commercialized PMN chemicals is appropriate even if similar risks from existing chemicals are not being addressed. In other words, regulatory or other action under the new chemicals followup program will not be driven by the priorities of the existing chemicals program. Instead, where action on chemicals subject to followup would encourage the development of data necessary for an adequate review of risks or would lead to an appropriate reduction in risks, without imposing undue burdens, the Office will not hesitate to act.